Reset Form Print Form

Government of District of Columbia Department of Health Care Finance

Idvynso™ (doravirine and islatravir)

Request Date: _____

PATIENT INFORMATION

Patient Medicaid ID: _____

Date of Birth: _____

Patient Last Name: _____

Patient First Name: _____ Middle Initial: _____

PRESCRIBER INFORMATION

Prescriber Last Name: _____

Prescriber First Name: _____

Prescriber Phone: _____

Prescriber Fax: _____

Prescriber DEA Number: _____

Prescriber NPI Number: _____

Prescriber Specialty: _____

PHARMACY INFORMATION

Pharmacy Name: _____

Pharmacy Phone: _____

Pharmacy Fax: _____

Pharmacy NPI Number: _____

Refer to FDA www.fda.gov for prescribing details and approved indications.

IDVYNSO™ BACKGROUND: www.merck.com/product/usa/pi_circulars/i/idvynso/idvynso_pi.pdf

The U.S. Food and Drug Administration (FDA) approved IDVYNSO™ (doravirine/islatravir) on April 20, 2026. This once-daily, two-drug regimen in a single-tablet (100 mg doravirine and 0.25 mg islatravir) is indicated for adults with virologically suppressed HIV 1 (**HIV 1 RNA <50 copies/mL**) on a stable antiretroviral regimen (**at least three months**) with **NO** history of virologic treatment failure and **NO** known doravirine resistance substitutions.

Patient's Name (Last, First): _____

PRIOR AUTHORIZATION CRITERIA

Instructions: Please carefully review the criteria described below and check all applicable boxes to determine treatment eligibility:

☐ The recipient must have Human Immunodeficiency Virus-1 (HIV-1).

☐ The recipient must be at least 18 years of age at start of treatment.

☐ The recipient currently must be virologically-suppressed as described in the indicated FDA approved Idvynso™ label that summarizes the outcome of clinical studies with **HIV-1 RNA less than 50 copies/mL**[1]. **Strongly recommend attachment of lab results**.

Recipient's HIV-1 RNA copies and date: _____.

☐ Since Idvynso™ is FDA indicated to replace a current antiretroviral regimen in patients with a HIV-1 RNA < 50 copies/mL, the recipient must currently be on a stable **(at least 3 months)** antiretroviral regimen with **NO** history of virologic treatment failure and **NO** known substitutions associated with resistance to doravirine.

☐ Genotypic Resistance Testing (prescriber must review current or past testing history to ensure the patient doesn't have any known HIV mutations or resistance-associated substitutions to doravarine)[2]. **Strongly recommend attachment of clinical notes/test results.**

Resistance-associated substitutions to doravarine testing status (resistant or sensitive) and date: _____

☐ Prescriber attests that the recipient's treatment history[3] was carefully reviewed. Lab and medical records must show the recipient never experienced virological treatment failure.

☐ Prescriber acknowledges that Idvynso™ is **contraindicated** when co-administer with strong cytochrome P450 (CYP)3A enzyme inducers. Strong CYP3A inducers **will decrease doravirine plasma concentrations** which will decrease the effectiveness of Idvynso™.

[1] **Suppression** is a broader term: any viral load below the detection threshold of HIV-1 RNA test (often 200 copies/mL) is considered suppressed. **Undetectable** is a stricter measure: the virus is so low it cannot be measured at all by standard tests **(often <50 copies/mL)**. All undetectable viral loads are suppressed, but not all suppressed viral loads are undetectable, some may still be measurable but very low.

[2] "In the IDVYNSO arm of Trial 051 (n=366), 5 participants had HIV-1 RNA ≥50 copies/mL at Week 48. Two participants had virologic failure with HIV-1 RNA >20,000 copies/mL at Week 4 and were ineligible for enrollment due to a prior history of virologic failure and/or doravirine resistance-associated substitutions. Both had NNRTI resistance-associated substitutions (A98A/G, K101A, K103K/N, V106V/I or M, Y188Y/L or L/W, F227L, and/or L228L/R), thymidine analog substitution.... Baseline NNRTI and NRTI resistance-associated substitutions from virologic failure on previous ART regimens likely contributed to the treatment outcome (HIV-1 RNA ≥50 copies/mL) at Week 48 in 4 participants receiving IDVYNSO in Trial 051 and Trial 052, **emphasizing the importance of having no prior virologic treatment failure before initiating IDVYNSO."**

[3] HIV treatment failure occurs when antiretroviral therapy (ART) is no longer able to control HIV infection, indicated by rising viral load, declining immune function, or the development of HIV-related illnesses.

Patient's Name (Last, First): _____

☐ Prescriber acknowledges that Idvynso™ is **contraindicated** when co-administered with lamivudine (3TC) or emtricitabine (FTC). 3TC and FTC are deoxycytidine kinase (dCK) substrates which **will decrease islatravir-triphosphate** (ISL-TP) levels resulting in decreased effectiveness of Idvynso™.

☐ Prescriber acknowledges that Idvynso™ co-administration with Nucleoside Antimetabolites (oncology drugs: www.merck.com/product/usa/pi_circulars/i/idvynso/idvynso_pi.pdf, which can decrease ISL-TP levels) or Moderate CYP3A Inducers (decreases doravirine levels) other than Idvynso™ modified dose instructions with rifabutin is **NOT** recommended.

☐ Prescriber attests to educate the recipient about recognizing and reporting signs or symptoms of severe skin reactions immediately. **Warning:** Severe skin reactions, including Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN) and Drug Rash with Eosinophilia and Systemic Symptoms (DRESS), have been reported and are potentially life-threatening if not recognized and treated promptly. Patients must immediately stop taking Idvynso™ and seek medical attention if a painful rash with mucosal involvement or a rash with constitutional symptoms develops.

☐ Prescriber attests that the recipient does **not** have any of the following conditions below. If the recipient does have any of the following conditions below, please check the applicable box.

- ☐ Is pregnant or plans to become pregnant. It is not known if Idvynso™ can harm an unborn baby.
- ☐ Is breastfeeding or plans to breastfeed. It is not known whether Idvynso™ passes into breast milk, and there are risks to the baby from HIV transmission or side effects.
- ☐ Has severe hepatic impairment (Child-Pugh Class C).
- ☐ Has an estimated GFR less than 30 mL/min/1.73 m^2.

*Please provide any additional information that would help in the decision-making process. Fax Clinical Documentation to **1-866-535-7622**.

LENGTH OF AUTHORIZATION CRITERIA

Length of authorization: **up to 6 months**

PRIOR AUTHORIZATION RENEWAL

☐ The recipient met and continues to meet the initial review criteria.

☐ The recipient has not experienced any treatment-restricting serious adverse effects, virological treatment failure, or resistance to Idvynso™ (doravirine/islatravir).

☐ Recipient's most recent HIV-1 RNA copies and date: _____.

☐ Recipient's most recent resistance-associated substitutions to dovarine testing status (resistant or sensitive) and date: _____

Patient's Name (Last, First): _____

DOSAGE AND ADMINISTRATION

The recommended dosage of Idvynso™ is one tablet taken orally once daily with or without food. If Idvynso™ is co-administered with rifabutin, take one tablet of Idvynso™ once daily as recommended followed by one tablet of doravirine (Pifeltro®) 100 mg approximately 12 hours after the dose of Idvynso™ for the duration of rifabutin co-administration. Because Idvynso™ is a complete regimen for the treatment of HIV-1 infection, co-administration with other antiretroviral medications for treatment of HIV-1 is not recommended.

By signature, the prescriber confirms the above information is complete, accurate, and verifiable by recipient's records.

Prescriber's Signature: _____ **Date:** _____

Fax to:
District of Columbia Pharmacy Program
Fax: 866-535-7622
Phone: 800-273-4962