Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

All Wales HIV-1 antiretroviral therapy prescribing guidelines

May 2026

This document has been prepared by a working group of the All Wales HIV Pharmacist Group and the All Wales Antiretroviral Prescribing Group, with support from the All Wales Prescribing Advisory Group (AWPAG) and the All Wales Therapeutics and Toxicology Centre (AWTTC), and has subsequently been endorsed by the All Wales Medicines Strategy Group (AWMSG).

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Abbreviations

AIDS, acquired immune deficiency syndrome

ART, antiretroviral therapy

AWMSG, All Wales Medicines Strategy Group

BHIVA, British HIV Association

BMI, body mass index

CKD, chronic kidney disease

CrCl, creatinine clearance

CVD, cardiovascular disease

EACS, European AIDS Clinical Society

eGFR, estimated glomerular filtration rate

HBsAg, hepatitis B surface antigen

HBV, hepatitis B virus

HIV-1, human immunodeficiency virus type 1

INSTI, integrase strand transfer inhibitor

IU, international units/ml

MDT, multidisciplinary team

NICE, National Institute for Health and Care Excellence

NNRTI, non-nucleoside reverse transcriptase inhibitor

NRTI, nucleoside reverse transcriptase inhibitor

RAM, resistance-associated mutation

Tenofovir-AF, tenofovir alafenamide fumarate

Tenofovir-DF, tenofovir disoproxil fumarate (can also be referred to as tenofovir DX or TDX in some literature, but, for the purposes of this guidance, will be referred to as tenofovir-DF)

1.0 Introduction

Antiretroviral therapy (ART) is licensed for the treatment of human immunodeficiency virus type 1 (HIV-1). The aim of ART is to suppress the viral load, reduce mortality and morbidity associated with HIV infection, reduce onwards transmission and prevent the development of acquired immune deficiency syndrome (AIDS). Over the years, treatment outcomes with ART have improved significantly with respect to clinical effectiveness and tolerability.[1]

1.1 Purpose

The purpose of the *All Wales HIV-1 antiretroviral therapy prescribing guidelines* is to support consistency across Wales in the evidence-based and prudent prescribing of ART for the treatment of HIV-1. The guidance aims to support clinicians and other healthcare professionals in the pharmacological management of HIV-1 to deliver good prescribing practice, optimise treatment to suppress the viral load while minimising the risk of adverse effects, and improve the person's health-related quality of life.

1.2 Objectives

- To provide prescribing guidance for clinicians in the pharmacological management of people living with HIV-1.
- To support prudent and evidence-based prescribing.
- To reduce the potential for medication-related adverse effects.
- To support a uniform approach to the prescribing of ART throughout Wales.

1.3 Scope

ART should only be prescribed by a specialist healthcare professional working within the area of HIV and adhering to the principles of prudent prescribing.[2,3] This document is written as a prescribing guide and relates to healthcare professionals who specialise in the management of people living with HIV-1 in Wales.

Some people may fall outside of this guideline, for example people under the age of 18 years, people who are pregnant, and people with genotypic resistance or those on treatment with a viral load of > 82 IU/ml*. These cases should be discussed with a senior clinician/multidisciplinary team (MDT). Complex cases can be discussed at the regional MDT. Examples of complex cases could include those involving multiple genotypic resistance and complex drug–drug interactions.

This guideline should be used in combination with national guidance. British HIV Association (BHIVA) guidelines have received an interim update in 2025 and changes to BHIVA-recommended ART prescribing practices are reflected in this guidance.

Prescribers must ensure that the decision to prescribe a medicine is made with consideration of equity and is responsible, appropriate and in line with current prescribing practice for people in NHS Wales, in accordance with All Wales

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*Equivalent to approximately > 50 copies/ml at the time of writing. Viral load results in Wales are reported in international units/ml (IU/ml). To convert to copies/ml, clinicians should refer to the conversion instructions on the laboratory HIV-1 viral load report on the Welsh Clinical Portal.

Medicines Strategy Group (AWMSG), National Institute for Health and Care Excellence (NICE), and local formulary advice.[4] Advice on the use of HIV-1 medicines that have been assessed by AWMSG is available on the All Wales Therapeutics and Toxicology Centre website at: Medicine recommendations. AWMSG prescribing advice is based on a rigorous decision-making process, taking into account clinical effectiveness and cost effectiveness. AWMSG advice has no impact on the licensed status of a medicine. Recommendations from AWMSG do not impact on the clinical freedom of the prescriber. However, a positive recommendation by AWMSG, subsequently endorsed by Welsh Government, places an obligation on health boards to fund accordingly.[4]

2.0 Starting treatment

Choice of treatment should be a joint decision between the person living with HIV-1 and the prescriber. This needs to be based upon clinical suitability, consideration of cost and informed choice.

The clinical team remain responsible for making sure that the choice is clinically suitable and in line with national prescribing guidelines.

Where several treatment options are considered clinically suitable, taking into account adherence, risk of resistance and informed choice, prescribers are advised to prescribe the lowest cost treatment option that is most appropriate for their patient.

Person-specific factors should be considered when constructing a regimen, and these should include:

- renal function (see Table 1 and 2 and section 7.0 for information on prescribing in renal disease/impairment)
- bone disease (see Table 1 and 2 for information on prescribing in bone disease)
- hepatitis B virus (HBV) co-infection (see Table 1 for information on prescribing in HBV co-infection)
- estimated cardiovascular risk (see Table 2 for information on prescribing in increased cardiovascular disease [CVD] risk)
- major psychiatric disorders, severe mood/psychotic disorders
- comorbidities
- pregnancy status
- a desire to conceive
- opportunistic infections
- swallowing difficulties or gastrointestinal absorption issues
- drug–drug interactions (see section 6.0 for information on drug–drug interactions)
- pill burden and polypharmacy

Viral factors such as resistance mutations and viral load should also be accounted for.

Table 1. Suggested starting ART regimens

Indication	Preferred regimens	Further information
Preferred starting regimen (including rapid start when resistance and hepatitis serology are unknown)	Emtricitabine/tenofovir-DF & dolutegravir	Once adherence is established and viral load is suppressed, it is advised that tenofovir-DF should be discontinued to reduce the risk of longer-term adverse drug reactions.[5] Lamivudine/dolutegravir (Dovato®) is suitable if HBsAg negative.†[1]
	Lamivudine/dolutegravir (Dovato®) & tenofovir-DF	
If single tablet regimen necessary OR **Renal disease** CrCl 30–60 ml/min*, decreasing eGFR or renal disease (NICE chronic kidney disease [CKD])	Lamivudine/dolutegravir (Dovato®)[6]	Lamivudine/dolutegravir (Dovato®) is suitable if viral load < 820,000 IU/ml‡, resistance profile allows and HBsAg negative.†[1]
OR **Bone disease** Confirmed osteoporosis, severe osteopenia (T-score less than −2), history of fragility fracture or a 10-year probability of a major osteoporotic fracture > 5% and/or a hip fracture > 1%[1]	Emtricitabine/tenofovir-AF/ bictegravir (Biktarvy®)	Emtricitabine/tenofovir-AF/ bictegravir (Biktarvy®) is suitable if HBV co-infection, virological resistance and/or adherence concerns are present.
HBV co-infection	Emtricitabine/tenofovir-DF & dolutegravir Emtricitabine/tenofovir-AF/ bictegravir (Biktarvy®)	Tenofovir-based regimen is needed.

*Dose adjustments or alternative regimens should be considered in CrCl < 30 ml/min.
†Caution if HBV non-immune or positive hepatitis B core antibody – refer to BHIVA guidance.
‡Equivalent to approximately < 500,000 copies/ml at the time of writing.

3.0 Switching treatment

Switching ART should only be done accounting for previous antiretroviral regimens, resistance history and adverse drug reactions.

Table 2. Suggested switching ART regimens (viral load < 82 IU/ml)*

Indication	Preferred regimens	Further information
Renal disease CrCl 30–60 ml/min†, decreasing eGFR or renal disease (NICE CKD) OR **Bone disease** Confirmed osteoporosis, severe osteopenia (T-score less than −2), history of fragility fracture or a 10-year probability of a major osteoporotic fracture > 5% and/or a hip fracture > 1%[1]	Lamivudine/ dolutegravir (Dovato®)	Lamivudine/dolutegravir (Dovato®) is suitable if no known or suspected resistance to the integrase inhibitor class, or lamivudine§ and if HBsAg negative.‡[1] Dose adjustment may be required in CrCl ≤ 30 ml/min (see section 7.0).
	Emtricitabine/ tenofovir-AF/ bictegravir (Biktarvy®)	Emtricitabine/tenofovir-AF/bictegravir (Biktarvy®) is suitable if HBV co-infection and/or, virological resistance. If tenofovir is required as part of the ART regimen, tenofovir-AF would be the preferred option in renal/bone disease.
Increased CVD risk QRisk3 > 10% estimated 10-year CVD risk Ensure the person is offered a statin (see BHIVA guidance on the use of statins for primary prevention of CVD in people living with HIV)	Lamivudine/ dolutegravir (Dovato®)	Lamivudine/dolutegravir (Dovato®) is suitable if no known or suspected resistance to the integrase inhibitor class, or lamivudine§ and if HBsAg negative.‡[1]
	Emtricitabine/ tenofovir-AF/ bictegravir (Biktarvy®)	Emtricitabine/tenofovir-AF/bictegravir (Biktarvy®) is suitable if HBV co-infection, virological resistance and/or adherence concerns.
	Avoid abacavir, particularly in people with increased cardiovascular risk, as abacavir is associated with an increased risk of major cardiovascular events.[7,8]	
Injectable ART alternative	Cabotegravir intramuscular (IM) injection (Vocabria®)[9] with rilpivirine IM injection (Rekambys®)	Please refer to section 8.0 for criteria for use.

*Equivalent to approximately < 50 copies/ml at the time of writing.
†Dose adjustments or alternative regimens should be considered in CrCl < 30 ml/min.
‡Caution if HBV non-immune or positive hepatitis B core antibody – refer to BHIVA guidance.
§Maintenance of NRTIs, lamivudine and emtricitabine, should be considered even in the presence of M184V. If prior resistance/virological failure discuss at local MDT/resistance meeting for suitability as emerging evidence suggests M184V mutation may not be a contraindication to use of lamivudine/dolutegravir (Dovato®).[1]

4.0 Alternative ART regimens

Alternative approaches or strategies may be considered depending on the individual circumstances, preferences and values of the person living with HIV.[1]

Some people may be on alternative regimens, including more than three drugs, usually in the context of complex resistance, drug–drug interactions, tolerability, persistent viraemia or other reasons. Complex ART regimens should be discussed at an MDT meeting and the rationale for a complex ART regimen should be clearly documented.

Note that the list of regimens in this guidance is not exhaustive. Please see the BHIVA guidance for other regimens to be considered in individual patient circumstances.

The person's ART regimen should be reviewed at least annually. Switches to cheaper generic equivalents should be made as they become available. Regimens containing abacavir, efavirenz, protease inhibitors and high-cost agents should be reviewed with a view to switching to more clinically appropriate or cost-effective regimens where possible.

Table 3. Suggested alternative ART regimens

Indication	Alternative regimens	Further information
Alternative regimens *There must be clear documentation in the health record of the rationale for prescribing*	Emtricitabine/tenofovir-DF & raltegravir	In treatment initiation, only suitable if viral load < 164,000 IU/ml*, caution in adherence concerns.
	Lamivudine/tenofovir-DF/doravirine (Delstrigo®)	Alternative if NNRTI needed.
	Emtricitabine/tenofovir-AF/darunavir/cobicistat (Symtuza®)	Suitable alternative if there is evidence of resistance or adherence concerns. Each individual case must be discussed and agreed at an MDT meeting before prescribing. The need for emtricitabine/tenofovir-AF/darunavir/cobicistat (Symtuza®) should be regularly reviewed. Regimens containing darunavir and ritonavir may be an alternative option.
*Equivalent to approximately < 100,000 copies/ml at the time of writing.		

5.0 Two-drug regimen switch options

Please refer to section 5 of the BHIVA guidance for information on switching to two-drug oral regimens in virological suppression – BHIVA guidelines on antiretroviral treatment for adults living with HIV-1 2022 (2025 interim update).

6.0 Drug–drug interactions

ART can have multiple drug–drug interactions, particularly those regimens including the pharmacokinetic enhancers ('boosters') ritonavir or cobicistat. For advice on drug–drug interactions see the HIV Drug Interactions website or discuss with the specialist HIV pharmacist.

There are also Medicines Advice Services across Wales supporting healthcare professionals with advice and information about medicines and these can be accessed here: Welsh Medicines Advice Service.

7.0 Renal impairment

For people with renal impairment discuss dose adjustments on an individual case basis with the specialist HIV pharmacist or the treating physician. A cautious approach must be taken to avoid underdosing, especially in people who are on dual ART.

8.0 Injectable ART

Cabotegravir and rilpivirine IM injections are a treatment option for people who are motivated to use injectable treatment.

8.1 Criteria for injectable ART use

People should meet the following criteria to receive injectable ART:[10,11]

- Have been on ART for at least 3–6 months and are virally suppressed typically to < 82 IU/ml*, and
- Have no known or suspected non-nucleoside reverse transcriptase inhibitor (NNRTI) or integrase strand transfer inhibitor (INSTI) resistance, and
- Have no history of virological failure on NNRTI- or INSTI-containing ART, and
- Can commit to 2-monthly attendance for injections, and
- Have engaged in shared decision-making and are aware of the small risk of virological failure, often with resistance, despite complete adherence and the potential implications for sustaining undetectable and therefore untransmittable levels (U=U), and
- Do not have a combination of body mass index (BMI) > 30 kg/m^2 and subtype A6, and
- Do not need a tenofovir-containing regimen for the treatment or prevention of HBV, and
- Are not considered at significant risk of HBV reactivation or re-infection.

*Equivalent to approximately < 50 copies/ml at the time of writing.

Long-acting cabotegravir/rilpivirine can be continued in people who may not meet the criteria above but are already virally suppressed on long-acting cabotegravir/ rilpivirine via a clinical trial; or as part of an alternative medicines access route, such as a compassionate access programme or individual patient funding request (IPFR).

In cases where all criteria are not met, eligibility should be discussed at the MDT meeting. Clear documentation and rationale for prescribing must be documented in the person's health record.

Long-acting cabotegravir/rilpivirine is not licensed for use in people with a non-suppressed viral load but off label use can be considered with caution in people who:

- Continue to have a detectable viral load on oral ART despite extensive support, and
- Are at high risk of disease progression based on CD4 count and/or HIV-related conditions, and
- Are able to commit to regular appointments, and
- Do not have resistance to cabotegravir and/or rilpivirine, and
- Are willing to accept the possibility of resistance emergence and limitation of treatment options.

Viral load should be monitored through:

- Two-monthly HIV RNA quantification for the first 6–12 months of injectable therapy;
- Thereafter, 4- to 6-monthly HIV RNA quantification in people without indicators of risk*, taking individual preference into account.

8.2 Oral lead-in for injectables

Oral lead-in with cabotegravir and rilpivirine tablets is optional but should be used for all individuals on etravirine, efavirenz or nevirapine and may be preferable in individuals where there are concerns with regards to tolerability.

If switching from etravirine- or efavirenz-based treatment:

- Use oral cabotegravir and higher-dose oral rilpivirine (50 mg) for 2 weeks followed by 2 weeks of standard dosing, or
- Use standard-dose oral cabotegravir and rilpivirine with additional two-NRTI cover from tenofovir-DF (or tenofovir-AF) plus emtricitabine or lamivudine.

If switching from nevirapine-based treatment:

- Use standard oral lead-in.

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*Subtype A6, history of viraemia on NNRTIs or INSTIs without resistance, starting long-acting cabotegravir/rilpivirine with detectable or recently detectable viral load, receipt of last injection at the end of the 7-day window period and, potentially, NNRTI polymorphisms (i.e. V106I and V179D/E) that are not recognised rilpivirine resistance-associated mutations (RAMs; i.e. L100I, K101E/P, E138A/G/K/Q/R, V179L/F, Y181C/I/V, Y188L, H221Y, F227C/L and M230I/L).

Remember to consider the potential drug–drug interactions with oral rilpivirine (see section 6.0).

9.0 Audit

The specialist HIV treating centre within each health board will be responsible for completing an audit to review the prescribing of ART within their cohort of patients. The audit will measure compliance to the ART guideline.

10.0 Review

Review of this guideline should take place every three years with the need for more regular or interim updates, such as specific updates based on national guidance or changes in the evidence base, highlighted to AWTTC by the clinical network.

11.0 Further information

- BHIVA guidelines on antiretroviral treatment for adults living with HIV-1 2022 (2025 interim update).
- Welsh Government HIV Action Plan for Wales 2023-2026
- BHIVA guidelines on the management of HIV in pregnancy and the postpartum period 2025
- European AIDS Clinical Society (EACS) Guidelines 2024

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