

Enclosure No:	7/AWMSG/0526
Agenda item No:	11 – All Wales HIV-1 antiretroviral therapy prescribing guidelines
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1.0 Action for AWMSG

AWMSG members are asked to consider the *All Wales HIV-1 antiretroviral therapy prescribing guidelines* document for endorsement. Consultation responses received in December 2025 and resulting actions are summarised at the end of the document. AWTTTC's equality and health impact assessment form is also enclosed.

2.0 Purpose

The *All Wales HIV-1 antiretroviral therapy prescribing guidelines* are written by a working group of the All Wales HIV Pharmacist Group and the All Wales Antiretroviral Prescribing Group (AWAPG). The intended audience is clinicians and healthcare professionals working in secondary care or specialist HIV/infectious diseases clinics who manage and treat people living with HIV-1 infection.

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 antiretroviral therapy (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 and improve health-related quality of life for people living with HIV-1.

The objectives of the guidelines are to:

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

2.1 Process

- June 2025: Draft document considered by AWPAG
- September 2025: Draft document considered by AWPAG
- November–December 2025: Draft document out for consultation
- March 2026: Consultation comments and responses considered by AWPAG for sign-off
- *May 2026: Document presented to AWMSG for endorsement*

2.2 Consultees

Consultees include, but are not limited to:

- Terrence Higgins Trust
- Fast-Track Cities
- Directors of Pharmacy
- Medical Directors
- Assistant Medical Directors
- Health Board Chief Executives
- Directors of Nursing
- Local Medical Committees
- Directors of Public Health
- General Practitioners Committee (GPC) Wales
- Royal College of General Practitioners (RCGP)
- British Medical Association (BMA) Cymru
- Llais Cymru
- Community Pharmacy Wales (CPW)
- Public Health Wales (PHW)
- Welsh Government
- NHS Wales Joint Commissioning Committee (JCC)
- National Institute for Health and Care Excellence (NICE)
- AWMSG members and deputies
- AWPAG members and deputies

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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 an All Wales HIV-1 antiretroviral prescribing guideline 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 within 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 Medicines Strategy Group (AWMSG), National Institute for Health and Care Excellence (NICE), and local formulary advice.⁴ Advice on the use of HIV-1

[‡]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.

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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
<p>Preferred starting regimen (including rapid start when resistance and hepatitis serology are unknown)</p>	<p>Emtricitabine/tenofovir-DF & dolutegravir</p> <p>Lamivudine/dolutegravir (<u>Dovato</u>[®]) & tenofovir-DF</p>	<p>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 (<u>Dovato</u>[®]) is suitable if HBsAg negative.^{††1}</p>
<p>If single tablet regimen necessary</p> <p><u>OR</u></p> <p>Renal disease CrCl 30–60 ml/min[†], decreasing eGFR or renal disease (NICE chronic kidney disease [CKD])</p> <p><u>OR</u></p> <p>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</p>	<p>Lamivudine/dolutegravir (<u>Dovato</u>[®])⁶</p> <p>Emtricitabine/tenofovir-AF/ bicitegravir (<u>Biktarvy</u>[®])</p>	<p>Lamivudine/dolutegravir (<u>Dovato</u>[®]) is suitable if viral load < 820,000 IU/ml^{**}, resistance profile allows and HBsAg negative.^{††1}</p> <p>Emtricitabine/tenofovir-AF/ bicitegravir (<u>Biktarvy</u>[®]) is suitable if HBV co-infection, virological resistance and/or adherence concerns are present.</p>
<p>HBV co-infection</p>	<p>Emtricitabine/tenofovir-DF & dolutegravir</p> <p>Emtricitabine/tenofovir-AF/ bicitegravir (<u>Biktarvy</u>[®])</p>	<p>Tenofovir-based regimen is needed.</p>
<p>[†]Dose adjustments or alternative regimens should be considered in CrCl < 30 ml/min. ^{**}Equivalent to approximately < 500,000 copies/ml at the time of writing. ^{††}Caution if HBV non-immune or positive hepatitis B core antibody – refer to BHIVA guidance.</p>		

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
<p>Renal disease CrCl 30–60 ml/min[†], decreasing eGFR or renal disease (NICE CKD)</p> <p><u>OR</u></p> <p>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</p>	<p>Lamivudine/dolutegravir (Dovato[®])</p>	<p>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).</p>
<p>Increased CVD risk QRisk3 > 10% estimated 10-year CVD risk</p> <p>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)</p>	<p>Lamivudine/dolutegravir (Dovato[®])</p> <p>Emtricitabine/tenofovir-AF/bictegravir (Biktarvy[®])</p>	<p>Lamivudine/dolutegravir (Dovato[®]) is suitable if no known or suspected resistance to the integrase inhibitor class, or lamivudine** and if HBsAg negative.^{††1}</p> <p>Emtricitabine/tenofovir-AF/bictegravir (Biktarvy[®]) is suitable if HBV co-infection, virological resistance and/or adherence concerns.</p> <p>Avoid abacavir, particularly in people with increased cardiovascular risk, as abacavir is associated with an increased risk of major cardiovascular events.^{7,8}</p>
<p>Injectable ART alternative</p>	<p>Cabotegravir intramuscular (IM) injection (Vocabria[®])⁹ with rilpivirine IM injection (Rekambys[®])</p>	<p>Please refer to Section 8.0 for criteria for use.</p>
<p>*Equivalent to approximately < 50 copies/ml at the time of writing. [†]Dose adjustments or alternative regimens should be considered in CrCl < 30 ml/min. **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 ^{††} Caution if HBV non-immune or positive hepatitis B core antibody – refer to BHIVA guidance.</p>		

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 <i>There must be clear documentation in the health record of the rationale for prescribing</i>	Emtricitabine/tenofovir-DF & raltegravir	In treatment initiation, only suitable if viral load < 164,000 IU/ml*, caution in adherence concerns.
	Lamivudine/tenofovir-DF/doravirine (<u>Delstrigo</u> [®])	Alternative if NNRTI needed.
	Emtricitabine/tenofovir-AF/darunavir/cobicistat (<u>Symtuza</u> [®])	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 (<u>Symtuza</u> [®]) 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/m² 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.

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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.

Remember to consider the potential drug–drug interactions with oral rilpivirine (see [Section 6.0](#)).

**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).

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 AWTTTC 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](#)

12.0 References

1. British HIV Association. BHIVA guidelines on antiretroviral treatment for adults living with HIV-1 2022 (2025 interim update). 2025. Available at: <https://bhiva.org/clinical-guideline/hiv-1-treatment-guidelines/>. Accessed October 2025.
2. Addis S, Holland-Hart D, Edwards A et al. Implementing Prudent Healthcare in the NHS in Wales; what are the barriers and enablers for clinicians? *J Eval Clin Pract*. 2019;25(1):104–110.
3. Welsh Government. Prudent healthcare. 2016. Available at: <https://www.gov.wales/prudent-healthcare>. Accessed August 2025.
4. All Wales Medicines Strategy Group. Prescribing dilemmas: A guide for prescribers. 2021 (Updated 2025). Available at: <https://awttc.nhs.wales/medicines-optimisation-and-safety/medicines-optimisation-guidance-resources-and-data/prescribing-guidance/prescribing-dilemmas-a-guide-for-prescribers/>. Accessed August 2025.
5. Cahn P, Madero JS, Arribas JR et al. Durable Efficacy of Dolutegravir Plus Lamivudine in Antiretroviral Treatment-Naive Adults With HIV-1 Infection: 96-Week Results From the GEMINI-1 and GEMINI-2 Randomized Clinical Trials. *J Acquir Immune Defic Syndr*. 2020;83(3):310–318.
6. Cahn P, Madero JS, Arribas JR et al. Dolutegravir plus lamivudine versus dolutegravir plus tenofovir disoproxil fumarate and emtricitabine in antiretroviral-naive adults with HIV-1 infection (GEMINI-1 and GEMINI-2): week 48 results from two multicentre, double-blind, randomised, non-inferiority, phase 3 trials. *The Lancet*. 2019;393(10167):143–155. Available at: <https://www.sciencedirect.com/science/article/pii/S0140673618324620>.
7. Fichtenbaum CJ, Malvestutto CD, Watanabe MG et al. Effects of antiretrovirals on major adverse cardiovascular events in the REPRIEVE trial: a longitudinal cohort analysis. *Lancet HIV*. 2025;12(7):e496–e505.
8. Medicines and Healthcare products Regulatory Agency. Abacavir: risk of myocardial infarction—update from epidemiological studies. 2014. Available at: <https://www.gov.uk/drug-safety-update/abacavir-risk-of-myocardial-infarction-update-from-epidemiological-studies>. Accessed September 2025.
9. emc. Vocabria 600 mg prolonged-release suspension for injection. 2025. Available at: <https://www.medicines.org.uk/emc/product/12957/smpc#gref>. Accessed September 2025.
10. British HIV Association. BHIVA guidance on long-acting cabotegravir/rilpivirine for antiretroviral therapy: non-technical summary. 2024. Available at: <https://bhiva.org/wp-content/uploads/2024/10/LA-CAB-RPV-for-ART-NTS.pdf>. Accessed September 2025.
11. National Institute for Health and Care Excellence. Cabotegravir with rilpivirine for treating HIV-1 (TA757). 2022. Available at: <https://www.nice.org.uk/guidance/ta757>. Accessed September 2025.

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All Wales HIV-1 antiretroviral therapy prescribing guidelines Consultation responses

Respondent and DOI	Page/section	Comment	Response and action taken
Dr Paul Emmett CEO North Wales LMC	Is there anything you would like to see added to the document?	Add explicit wording confirming that ART prescribing remains specialist-only and GPs should not initiate or switch ART.	Wording is included on page 3.
		Add requirement for HIV specialists to share medication lists with GPs , respecting confidentiality, to prevent missed diagnoses and adverse drug interactions. These can then be entered onto the patient medication screen as "hospital only" medications so interactions immediately pop up as alerts	Communication between primary and secondary care is outside the remit of this document. From discussion with Welsh HCPs working in the area, in practice, GPs should be written to as standard with the patient's consent. When the patient has not consented or does not wish for this to be done, it is not.
	Is there anything you would like to see removed from the document?	Nil obvious as a GP	Thank you for your comments.
Dr Simon Braybrook Butetown Medical Practice	Is there anything you would like to see added to the document?	The option for GPs to prescribe ARVs as an enhanced service	Outside the scope of this guidance. Highlight as an implementation consideration or future consideration. Service not currently available in Wales.
	P3 Line 68	<p>I recognise the need for prescribers to be appropriately trained. However, there are GPs such as myself who would be very keen to prescribe as an enhanced service. This would obviously need to be in partnership with specialist services, probably focussing on maintenance prescriptions following initiation. There will obviously be some patients who do not wish for their primary care provider to be part of their care. However, there would also be some who many prefer to have prescriptions issues close to home.</p> <p>Enhanced service prescribing is already being used in other specialist areas such as prescribing hormones for transgender patients and Buvirdal prescribing for substance misuse treatment. I would be very keen to see enhanced service prescribing for ARV treatment also.</p>	Thank you for the insight and feedback. As above.
Respondent 3: Cardiff and Vale UHB	Introduction 49	The title is "Antiretroviral Prescribing Guidelines", however the introduction and guideline talks about "Antiretroviral therapy". I would value complete clarity as to whether the prescribing of antiretrovirals for PREP are covered by this guidance or whether this is active therapy only in HIV positive patients only.	<p>The scope of the document is for the treatment of HIV. The document and title have been updated.</p> <p>PrEP could be discussed as potential future work. Link to BHIVA for now.</p>

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Dr Ushan Andrady Betsi Cadwaladr University Health Board	Is there anything you would like to see added to the document?	Table 2, p6 -include definition of high risk for FRAX/percentage (see 29 BHIVA guidance) like it has already been done for QRISK3 score - where the actual figure (>10%) is documented. It is detailed in the BHIVA guideline so the alternative could be just to reference the BHIVA guideline like it has been for the hepatitis B reactivation.	Added in figures re FRAX.
	Is there anything you would like to see removed from the document?	Nothing to be removed but some differences of opinion around the units that should be used for the HIV viral load. There were some clinicians who commented that they would prefer the HIV viral load to be expressed in copies per ml in line with other published guidelines. Whereas others felt that these guidelines were clear and their previous concerns around the use of IU/ml, particularly around if the conversion factor were to alter, were encompassed/addressed within the guidelines	Reviewed with input of the All Wales Antiretroviral Prescribing Group and it has been decided to leave as is for audience and ease of use.
		Consider removing words written in full in the tables that are including in the abbreviations list at the beginning e.g. CrCl, FRAX, TDF, TAF	Abbreviations list at front of the doc.
	P2 line 45	Consider changing TDF to TDX tenofovir disoproxil for consistency with BHIVA guidelines	This was taken for consideration to the All Wales Antiretroviral Prescribing Group and it was decided to stay with the original text as this is what the intended audiences are familiar with and for consistency. Explanation of alternative names at beginning/glossary added.
	P5 line 125 Top right-hand box	Add HBV cautions to comments about removing TDF from the regimen–caution if HBV non-immune or positive hep B core antibody	Added cautions back in.
	P5 line 128	Include side-effects/ADRs as other factors to account for before switching ART	Added.
	P7 line 140	Add “at least annually as per BHIVA guidelines” to regular review of person’s ART regimen	Added.
	P10 line 225	Consider changing review period to 2 years or longer	Added in, requirement less frequent but also updates as required. Suggest as per AWTTTC process and yearly review via All Wales HIV network with need for interim updates flagged to AWTTTC by clinical network.
Dr Ana Milinkovic ViiV Healthcare <i>(DOI - Full time employee ViiV Healthcare UK)</i>	Is there anything you would like to see added to the document?	Priority Recommendation 1: ViiV Healthcare recommends addition of Dovato alone as a preferred regimen to align with the licenced indication for use of Dovato as a complete antiretroviral regimen, align with the British HIV Association (BHIVA) guidelines on antiretroviral treatment for adults living with HIV-1 (2025 interim update) ¹ , and the literature evidencing Dovato use	Discussion with All Wales Antiretroviral Prescribing Group reflects preferred clinical practice in Wales. Table recommends that a preferred starting regimen is Dovato plus tenofovir-Df

¹ BHIVA guidelines on antiretroviral treatment for adults living with HIV-1 2022 (2025 interim update). Accessible from: <https://bhiva.org/wp-content/uploads/2025/10/BHIVA-guidelines-on-antiretroviral-treatment-for-adults-living-with-HIV-1-2025-interim-update.pdf>. Accessed: Dec 2025.

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		in people naïve to treatment in GEMINI 1&2 studies ² , STAT3, and D2ARLING ⁴	and states that tenofovir-DF should be discontinued when VL suppressed to reduce the risk of longer-term adverse drug reactions.
Is there anything you would like to see removed from the document?		<p>Cabotegravir and Rilpivirine Long-Acting Injectables Priority Recommendation 2: ViiV Healthcare recommends removal of the phrase “for people who find taking daily tablets challenging”. In Section 10.0 of the draft guidelines, the writing group recommend cabotegravir and rilpivirine intramuscular injections are a treatment option for people who “find taking daily tablets challenging”. To align with the BHIVA guidelines on antiretroviral treatment for adults living with HIV-1 (2025 interim update)¹, it is recommended that cabotegravir and rilpivirine long acting is for people who are “motivated to use injectable treatment”.</p>	Reviewed with the All Wales Antiretroviral Prescribing Group. Alignment with BHIVA and NICE guidance. The phrase “for people who find taking daily tablets challenging” has been removed and replaced with ‘for people who are motivated to use injectable treatment’
		<p>Recommendation 3: ViiV Healthcare recommends removal of the additional dosing oral lead in (OLI) if switching from Efavirenz (EFV) or Etravirine (ETR). Section 10.2 of the draft guideline recommends additional dosing OLI (or standard dosing + two additional NRTIs) if switching from EFV or ETR. The recommendation for an oral lead-in with an alternative 50mg Rilpivirine dose or the addition of NRTIs after a switch from Efavirenz is not in line with the Rilpivirine or Cabotegravir oral tablet Summary of Product Characteristics (SmPCs)^{5,6}. Switching without dose modifications is also permitted in the Dolutegravir/Rilpivirine SmPC⁷. Data from the ATLAS (Q4W)⁸ and ATLAS-2M (Q4W and Q8W)⁹ studies show that the majority of participants who switched from NNRTI-containing regimens (most commonly Efavirenz 32% and 39% in ATLAS and ATLAS-2M, respectively) where the dose of oral Rilpivirine was not increased during OLI, showed that virological suppression was maintained during the OLI and subsequently on LA cabotegravir + rilpivirine well after the residual induction affect from Etravirine/Efavirenz had worn off. There were no clinical virological failures (CVFs) during the oral</p>	Reviewed with the All Wales Antiretroviral Prescribing Group. Still part of BHIVA guidance – not covered in SmPC, but aligns with BHIVA. Leave as is.

² Ait-Khaled M, et al. Impact of treatment adherence on efficacy of dolutegravir plus lamivudine and dolutegravir plus tenofovir disoproxil fumarate/emtricitabine: pooled analysis of the GEMINI-1 and GEMINI-2 clinical studies. HIV Res Clin Pract. 2021 Dec 9;23(1):9-14. Epub 2021 Dec 16. PMID: 34913844

³ Rolle CP, et al. Dolutegravir/lamivudine as a first-line regimen in a test-and-treat setting for newly diagnosed people living with HIV. AIDS. 2021 Oct 1;35(12):1957-1965. doi: 10.1097/QAD.0000000000002979. PMID: 34115650; PMCID: PMC8462441.

⁴ Cordova E, et al. Efficacy of dolutegravir plus lamivudine in treatment-naïve people living with HIV without baseline drug-resistance testing available (D2ARLING): 48-week results of a phase 4, randomised, open-label, non-inferiority trial. Lancet HIV. 2025 Feb;12(2):e95-e104. doi: 10.1016/S2352-3018(24)00294-7. Epub 2025 Jan 15. PMID: 39826566.

⁵ VOCABRIA (cabotegravir) 30 mg film-coated tablets Summary of Product Characteristics (SmPC)

⁶ EDURANT (rilpivirine) 25 mg film-coated tablets Summary of Product Characteristics (SmPC)

⁷ JULUCA (dolutegravir/rilpivirine) Summary of Product Characteristics (SmPC)

⁸ Swindells S, et al. Long-Acting Cabotegravir and Rilpivirine for Maintenance of HIV-1 Suppression. N Engl J Med. 2020 Mar 19;382(12):1112-1123. doi: 10.1056/NEJMoa1904398. Epub 2020 Mar 4. PMID: 32130809. ATLAS-2M

⁹ Overton ET, et al. Long-acting cabotegravir and rilpivirine dosed every 2 months in adults with HIV-1 infection (ATLAS-2M), 48-week results: a randomised, multicentre, open-label, phase 3b, non-inferiority study. Lancet. 2021 Dec 19;396(10267):1994-2005. doi: 10.1016/S0140-6736(20)32666-0. Epub 2020 Dec 9. PMID: 33308425.

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	<p>lead-in phase in those switching from ETR or EFV during the period of concern from residual induction, without additional ARTs being required. In the ATLAS trial (Q4W)⁸, 155 study participants started cabotegravir + rilpivirine by standard OLI, followed by the four-weekly LA injectable regimen. In the ATLAS-2M⁹ trial, following standard oral lead-in, 151 (four-weekly) and 156 (eight-weekly) study participants, respectively, began injectable therapy. Week 48 snapshot analysis outcomes for these participants were similar to the subgroups switching from other 3rd class agents (PI or INSTI).</p> <p>Additionally, pooled pharmacokinetic analyses from SWORD-1 and SWORD-2^{10, 11} with the two-drug regimen Dolutegravir/Rilpivirine showed that Rilpivirine trough concentrations were comparable to historical controls at weeks four, twenty-four and forty-eight following switch from an INI-, NNRTI-, or PI-based regimen using the standard 25mg dose. Additionally, Dolutegravir and Rilpivirine trough concentrations were measured over time during the initial post-switch period in the first 20 subjects (in the NNRTI subset who switched from Efavirenz or Nevirapine to Dolutegravir/Rilpivirine). These extra sampling results showed that the Dolutegravir and Rilpivirine pre-dose plasma concentration (C₀) increased from Week two through Week four post-switch. Therefore, whilst we recognise the theoretical risk described in switching from NNRTIs to oral Rilpivirine as described in Section 10.2 of the draft All Wales Guidance, increasing the Rilpivirine dose during the oral lead-in phase, adding additional NRTI cover and/or administering three intramuscular Cabotegravir and Rilpivirine doses prior to commencing two-monthly dosing is both outside of the licenced recommendations and not supported by the available evidence. We therefore ask the Writing Group that the recommendations in Section 10.2 of the draft guidance be made consistent with both the evidence described above as well as the recommendations in the respective Vocabria and Rekambys SmPCs^{12 13}.</p>	
	<p>Dolutegravir/Lamivudine Recommendation 4: ViiV Healthcare recommends removal of the “< 820,000 IU/ml” viral load cut off for use of Dovato, given the recent DOLCE¹⁴ high viral load data showing equivalent suppression compared to three drug dolutegravir based therapy.</p>	<p>R4 Reviewed with the All Wales Antiretroviral Prescribing Group. The group suggests leaving as is to reflect current preferred clinical practice and alignment with BHIVA.</p>
	<p>Recommendation 5: ViiV Healthcare recommends removal of “caution if HBV non-immune, positive hepatitis B core antibody” and change this to “no</p>	<p>R5 Reviewed with the All Wales Antiretroviral Prescribing Group.</p>

¹⁰ Aboud M, et al. Efficacy and safety of dolutegravir-rilpivirine for maintenance of virological suppression in adults with HIV-1: 100-week data from the randomised, open-label, phase 3 SWORD-1 and SWORD-2 studies. *Lancet HIV*. 2019 Sep;6(9):e576-e587. doi: 10.1016/S2352-3018(19)30149-3. Epub 2019 Jul 12. PMID: 31307948.

¹¹ Aboud M, et al. Efficacy and safety of dolutegravir-rilpivirine for maintenance of virological suppression in adults with HIV-1: 100-week data from the randomised, open-label, phase 3 SWORD-1 and SWORD-2 studies. *Lancet HIV*. 2019 Sep;6(9):e576-e587. doi: 10.1016/S2352-3018(19)30149-3. Epub 2019 Jul 12. PMID: 31307948.

¹² VOCABRIA (cabotegravir) 600 mg suspension for injection Summary of Product Characteristics (SmPC)

¹³ REKAMBYS (rilpivirine) 900 mg suspension for injection Summary of Product Characteristics (SmPC)

¹⁴ Figueroa MI, et al. DOLCE study group. Efficacy and Safety of Dual Therapy With Dolutegravir/Lamivudine in Treatment-naive Persons With CD4 Counts <200/mm³: 48-Week Results of the DOLCE Study. *Clin Infect Dis*. 2025 Aug 28;ciaf415. doi: 10.1093/cid/ciaf415. PMID: 40874763.

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		requirement for tenofovir for hepatitis B treatment or prevention” to mirror BHIVA guideline language.	Wording reviewed to avoid risk of not monitoring. Leave context as is.
		Recommendation 6: ViiV Healthcare recommends removal of ‘good adherence’ for the recommendation of Dovato in table 2 given equivalent adherence-based outcomes in GEMINI-1&2 studies2	R6 Reviewed with the All Wales Antiretroviral Prescribing Group. Removed.
		Recommendation 7: ViiV Healthcare recommends Removal of ‘no previous virological failure’ for the recommendation of Dovato in table 2 and replace this with the licensed indication of ‘with no known or suspected resistance to the integrase inhibitor class, or lamivudine’	R7 Changed.
	Line 162	ViiV recommends removal of the recommendation of extra caution of 2DR underdosing. To our knowledge there is not specific evidence to support additional caution for all 2DR based therapies in those with renal impairment for underdosing risk. Neither DTG/3TC, DTG/RPV or CAB/RPV have been shown to have decreased exposure in those with renal impairment.	Reviewed with the All Wales Antiretroviral Prescribing Group. Consideration of non-specialists’ settings/admissions. Wording reviewed re lamivudine. Aim is to be accessible for all ward pharmacists and monitoring parameters.
	Page 125, Table 1	ViiV Healthcare recommends addition of Dovato alone as a preferred regimen given the indication of Dovato as a complete antiretroviral regimen, and to align with the BHIVA guidelines.	As above.
	Page 125, Table 1	ViiV Healthcare recommends removal of the “< 820,000 IU/ml” viral load cut off for use of Dovato. Given the recent DOLCE14 high viral load data showing equivalent suppression compared to three drug dolutegravir based therapy.	As above.
	Page 125, Table 1 & Line 129 Table 2	ViiV Healthcare recommends change of “Caution if HBV non-immune, positive hepatitis B core antibody” to “No requirement for tenofovir for hepatitis B treatment or prevention” to mirror BHIVA guideline language.	As above.
Dionysios Ntais MSD (UK) Ltd <i>(DOI - Pharmaceutical supplier, including HIV medicines)</i>	Is there anything you would like to see added to the document?	No	Thank you for your comments
	Is there anything you would like to see removed from the document?	No	Thank you for your comments
	N/A	MSD acknowledge the update to the All Wales HIV-1 Antiretroviral Prescribing Guidelines	Thank you for your comments
	Section 4.0	MSD acknowledge the upfront discussion of the importance of treatment choice, which should be a joint decision between the person living with HIV-1 and the prescriber, taking into account clinical needs and patient preferences	Thank you for your comments
	N/A	MSD have no further comments	Thank you for your comments

Equality and Health Impact Assessment All Wales HIV-1 antiretroviral therapy prescribing guidelines

AWTTC will fill in an Equality and Health Impact Assessment in parallel with each development stage of our projects. This will help us to follow the five ways of working for public bodies, and work to achieving the wellbeing goals, outlined in the Well-Being of Future Generations (Wales) Act 2015.

Date: 06/05/26

1.	AWTTC contact details	Tel: 02921 826900 Email: awttc@wales.nhs.uk
2.	State the objectives of the project.	<p>The purpose of the <i>All Wales HIV-1 antiretroviral therapy prescribing guidelines</i> is to support consistency across Wales in the evidence-based and cost-effective 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 and improve health-related quality of life for people living with HIV-1.</p> <p>The project aims to:</p> <ul style="list-style-type: none"> • Provide prescribing guidance for clinicians in the pharmacological management of HIV-1. • Support cost-effective and evidence-based prescribing. • Reduce the potential for medication-related adverse effects. • Support a uniform approach to the prescribing of ART throughout Wales. <p>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. This guideline aligns with the Welsh Government's HIV Action Plan for Wales 2023-2026.</p>
3.	Evidence and background information considered. For example: <ul style="list-style-type: none"> • population data 	<ul style="list-style-type: none"> • BHIVA guidelines on antiretroviral treatment for adults living with HIV-1 2022 (2025 interim update) • Cardiff and Vale HIV Antiretroviral Prescribing Guidelines version 10.1



	<ul style="list-style-type: none">• staff and service users' data, as applicable• needs assessment• engagement and involvement findings• research• good practice guidelines• participant knowledge• list of stakeholders and how stakeholders have engaged in the development stages• comments from those involved in the designing and development stages <p>Population pyramids are available from Public Health Wales Observatory.</p>	<ul style="list-style-type: none">• Betsi Cadwaladr University Health Board (BCUHB) HIV-1 Antiretroviral Prescribing Guidelines -MM80 V1.0• EACS guidelines version 12.0 October 2023. Available online at guidelines-12.0.pdf (eacsociety.org)• Vocabria 600 mg prolonged-release suspension for injection – Summary of Product Characteristics (SmPC) – (emc) (medicines.org.uk) <p>The document has been developed by a working group of the All Wales HIV Pharmacist Group and the All Wales Antiretroviral Prescribing Group (AWAPG). Ratification at an All Wales level will reduce the risk of version changes when adopted by each health board.</p>
4.	Who will this project affect?	<p>This project will affect people being treated for HIV-1 and aims to support good prescribing practice, thereby optimising treatment to suppress the viral load and improving quality of life.</p> <p>The project will also affect clinicians and healthcare professionals in secondary care or specialist HIV/infectious diseases clinics who will be supported to manage and treat people with HIV-1 infection with a consistent, evidence-based and prudent approach.</p>

5.0 EQIA – How will the project impact on people?

Questions in this section relate to the impact on people based on the 'protected characteristics' of the Equality Act 2010, and other factors.

How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/mitigation	Actions taken (and who by).
<p>5.1 Age For most purposes, the main categories are people aged:</p> <ul style="list-style-type: none"> • under 18 years; • between 18 and 65 years; • over 65 years. 	<p>We do not expect a potential negative, or unequal, impact on people based on their age. This guideline will not be applicable to children under the age of 18 years. Prescribing of ART for children may differ to the treatment of adults with HIV-1 due to licensing of medication, safety and evidence of efficacy in the paediatric population. The guideline does account for other age groups including an increasing elderly population who may have multiple co-morbidities, and ART is tailored to the needs and health of each individual. The guideline takes into account renal function, bone density and other morbidities commonly associated with old age. The care and treatment of all people under the age of 18 years (whom this guideline does not apply to) will be in the specialist tertiary centre.</p>		
<p>5.2 Persons with a disability as defined in the Equality Act 2010 Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes.</p>	<p>We do not expect a potential negative, or unequal, impact on people with a disability. A history of an individual's mental health will be taken into consideration when deciding on treatment options as some ART can cause side effects that may worsen the mental health condition. This is important to reduce risk of medication associated harm.</p>	<p>All related documents published on the AWTTC website will meet accessibility requirements. Any patient-facing materials will also</p>	



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/mitigation	Actions taken (and who by).
	This guideline provides options for treatment for different types of disability for example there are options for single tablet regimens (STR) to reduce pill burden for individuals who struggle with compliance due to disability or other cause.	be produced as easy-read formats.	
5.3 People of different genders: Consider men, women, people undergoing gender reassignment. N.B. Gender-reassignment is anyone who proposes to, starts, is going through or who has completed a process to change his or her gender with or without going through any medical procedures. Sometimes referred to as Trans or Transgender.	We do not expect a potential negative, or unequal, impact on people based on their gender, or on people undergoing gender reassignment.		
5.4 People who are married or who have a civil partner.	We do not expect a potential negative, or unequal, impact on people based on their marital status or being in a civil partnership.		
5.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding. They are protected for 26 weeks after having a baby whether or not they are on maternity leave.	We do not expect a potential negative, or unequal, impact on women who are expecting a baby, are breastfeeding, or are on a break from work after having a baby. Treatment options for pregnant women will be outside the scope of this guideline. Positive: Treatment options for this group of individuals will be based on national guidelines and safety with support from the local multidisciplinary team (MDT), including paediatric and maternity services. Pregnancy and post-		



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/mitigation	Actions taken (and who by).
	<p>partum mothers will be offered the same support as all other people living with HIV-1, but treatment options will be tailored to the individual based on resistance report, viral load, CD4 count and the safety of the medication in pregnancy. The treatment and recommendations for the management of all pregnant and breastfeeding mothers with HIV-1 will be supported by the local MDT. A separate guideline and treatment pathway is already in place to support this.</p>		
<p>5.6 People according to their race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies and travellers, migrant workers. The Runnymede Trust</p>	<p>We do not expect a potential negative, or unequal, impact on people of a different race, nationality, colour, culture or ethnic origin. People of different races and ethnicities can have varying responses to medicines. Some race and ethnicity groups are predisposed to genetic factors that increase cardiovascular risks. Some forms of ART are contraindicated if the cardiovascular risk is high. The guideline accounts for pre-disposing factors due to race and ethnicity such as cardiovascular risk and provides tailored treatment options to account for this.</p>	<p>Consider highlighting in the document that people of different races and ethnicities can have varying responses to medicines.</p>	
<p>5.7 People with a religion or belief or with no religion or belief. The term 'religion' includes a religious or philosophical belief. Implications of religious beliefs on selection of medicines (BMJ)</p>	<p>We do not expect a potential negative, or unequal, impact on people who have a religion or belief, or people with no religion of belief. Some medicines are made from certain animal products and people might not want to take them because of religion or belief.</p>	<p>Note to refer to product literature for further information on medicines e.g. SmPC.</p>	



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/mitigation	Actions taken (and who by).
In practice: guidance on religion, personal values and beliefs (General Pharmaceutical Council)			
5.8 People who are attracted to other people of: <ul style="list-style-type: none"> the opposite sex (heterosexual); the same sex (lesbian or gay); both sexes (bisexual). Stonewall	<p>We do not expect a potential negative, or unequal, impact on people based on who they are attracted to.</p> <p>Further information and guidance will be provided to all individuals on safe sex practice to reduce the risk of sexual transmission of HIV-1.</p>		
5.9 People who communicate using the Welsh language in terms of correspondence, information leaflets, or service plans and design.	<p>We do not expect a potential negative, or unequal, impact on people who communicate using the Welsh language.</p>	<p>Any patient-facing materials will be produced in Welsh and English, in line with the Welsh language standards, including easy-read booklets.</p>	
5.10 People according to their income related group.	<p>We do not expect a potential negative, or unequal, impact on people based on their income-related group.</p> <p>This guideline will apply to all individuals over the age of 18 years irrespective of their social economic status. All individuals will have equal access to treatment.</p>		
5.11 People according to where they live.	<p>We do not expect a potential negative, or unequal, impact on people based on where they live.</p>		



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/mitigation	Actions taken (and who by).
<p>5.12 Consider others who face health inequalities, such as:</p> <ul style="list-style-type: none"> • Looked after and accommodated children and young people • Carers: paid/unpaid, family members • People who are homeless or those who experience homelessness: people on the street; those staying temporarily with friends/family; those in hostels/B&Bs • People involved in the criminal justice system: offenders in prison or on probation, ex-offenders • People with addictions and substance misuse problems • People who have poor literacy • People living in remote, rural and island locations 	<p>We do not expect a potential negative, or unequal, impact on people who face health inequalities.</p> <p>This guideline will apply to all individuals over the age of 18 years irrespective of their characteristics and social economic status. All individuals will have equal access to treatment.</p>		
<p>5.13 Consider any other groups and risk factors relevant to this project.</p>			

6.0 HIA – How will the project impact on the health and wellbeing of people in Wales and help address inequalities in health?

Questions in this section relate to the impact on the overall health of individual people, and the impact on the population in Wales.

How will the project impact on, or affect:	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/mitigation	Actions taken (and who by)
6.1 People being able to access the service offered.	We do not expect a potential negative, or unequal, impact on people's ability to access the service offered.		
6.2 People being able to improve or maintain healthy lifestyles.	We do not expect a potential negative, or unequal, impact on people's ability to improve or maintain healthy lifestyles.		
6.3 People in terms of their income and employment status.	We do not expect a potential negative, or unequal, impact on people in terms of their income and employment status.		
6.4 People in terms of their use of the physical environment.	We do not expect a potential negative, or unequal, impact on people's use of the physical environment.		
6.5 People in terms of social and community influences on their health.	We do not expect a potential negative, or unequal, impact on people in terms of social and community influences on their health.		
6.6 People in terms of macro-economic, environmental and sustainability factors.	We do not expect a potential negative, or unequal, impact on people in terms of macroeconomic, environmental and sustainability factors.		



7.0 Please fill in section 7.1 after completing the EqHIA, and fill in the action plan.

<p>7.1 Please summarise the potential positive and/or negative impacts of the project.</p>	<p>Age: This guideline will not be applicable to children under the age of 18 years. Prescribing of ART for children may differ to the treatment of adults with HIV-1 due to licensing of medication, safety and evidence of efficacy in the paediatric population. The care and treatment of all patients under the age of 18 years will be in the specialist tertiary centre.</p> <p>The guideline does account for other age groups including an increasing elderly population who may have multiple co-morbidities, and ART is tailored to the needs and health of each individual. The guideline takes into account renal function, bone density and other morbidities commonly associated with old age.</p> <p>Disability: A history of an individual’s mental health will be taken into consideration when deciding on treatment options as some ART can cause side effects that may worsen the mental health condition. This is important to reduce risk of medication associated harm.</p> <p>This guideline provides options for treatment for different types of disability, for example there are options for STRs to reduce pill burden for individuals who struggle with compliance due to disability or other causes.</p> <p>Pregnancy, post-partum or breastfeeding: Treatment options for pregnant women will be outside the scope of this guideline. Treatment options for this group of individuals will be based on national guidelines and safety with support from the local MDT, including paediatric and maternity services. Pregnancy and post-partum mothers will be offered the same support as all other people living with HIV-1, but treatment options will be tailored to the individual based on resistance report, viral load, CD4 count and the safety of the medication in pregnancy. The treatment and recommendations for the management of all pregnant and breastfeeding mothers with HIV-1 will be supported by the local MDT. A separate guideline and treatment pathway is already in place to support this.</p> <p>Race, nationality, colour, culture or ethnic origin: People of different races and ethnicities can have varying responses to medicines. Some race and ethnicity groups are predisposed to genetic factors that increase cardiovascular risks. Some forms of ART are contraindicated if the cardiovascular risk is high.</p>
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Action plan for mitigation or improvement and implementation

	Action	Lead(s)	Timescale	Actions taken (state who by)
7.2 What are the key actions identified as a result of completing the EqHIA?	<p>Disability: All related documents published on the AWTTC website will meet accessibility requirements. Any patient-facing materials will also be produced as easy-read formats.</p> <p>Welsh language: Any patient-facing materials will be produced in Welsh and English, in line with the Welsh language standards, including easy-read booklets.</p>			
Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment needed?				
7.4 What are the next steps?	Document to be considered for endorsement by AWMSG	AWTTC	May 2026	
7.5 Review of project and EqHIA		AWTTC	[TBC]	

AWTTC's EqHIA template is adapted from the Cardiff & Vale University Health Board EHIA template.