Worcestershire Acute Hospitals NHS Trust

Guideline for the Use of Injectable Cabotegravir and Rilpivirine in Adults Living with HIV-1

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

Introduction

Cabotegravir and rilpivirine given by intramuscular injection is recommended for routine commissioning for the treatment of adults living with HIV-1.

NICE have acknowledged in their technology appraisal that cabotegravir and rilpivirine meets an unmet need for adults living with HIV-1 by offering an alternative to a daily oral regimen. This may be advantageous for those who are particularly concerned about stigma and disclosure of their HIV status, or those wishing to reduce their burden of taking daily tablets for example. Any/all of these considerations may have a negative impact on the lives of those living with HIV.

This guideline is for use by the following staff groups:

- Consultant in Infectious Diseases or Genitourinary Medicine
- Registrar in Infectious Diseases
- Lead Pharmacist HIV & Hepatitis C
- Clinical Nurse Specialist in HIV

Lead Clinician(s)

Rachael Leese	Lead Pharmacist HIV & Hepatitis C
Dr Mark Roberts	Lead Consultant in Infectious Diseases
Caroline Lister	Directorate Manager Infectious Diseases
Approved by *Infectious Diseases Directorate Meeting* on:	19th February 2024
Approved by Medicines Safety Committee on: *Where medicines included in guideline*	12th June 2024
Review Date: This is the most current document and should be used until a revised version is in place	19th February 2027

Key amendments to this guideline

Date	Amendment	Approved by:
February 24	New document approved	Infectious Diseases Directorate

Scope

- Injectable cabotegravir and rilpivirine has been extensively studied in large scale, multicentre randomised controlled trials, most notable are the ATLAS and FLAIR trials which both demonstrated non-inferiority to oral antiretroviral (ART) therapy.
- Cabotegravir and rilpivirine is administered as 2 separate intramuscular injections into the gluteal muscles. The dosing regimen either commences with a 28-30 day oral cabotegravir and rilpivirine lead-in, followed by monthly initiation injections for 2 consecutive months or direct to initiation injections for 2 consecutive months from current oral ART. Thereafter, continuation injections are given every 2 months. These should be commenced only if the patient is confirmed as virologically supressed prior to injectable therapy on their current oral ART and have no known resistance or prior virological failure with any drugs within the NNRTIs (non-nucleoside reverse transcriptase inhibitors) or INSTI (integrase) drug classes.
- This GUIDELINE outlines the WAHNHST procedure for the use of injectable cabotegravir and rilpivirine in adults living with HIV-1 to be followed by members of the Infectious Diseases BBV (Blood Borne Virus) Team.

- Acute Trust HIV Clinics offering monthly injectable cabotegravir/ rilpivirine clinics from 1st April 2024 are:
    - Sorrell Suite, Worcestershire Royal Hospital, Worcester
    - Arrowside Clinic, Alexandra Hospital, Redditch

Key Staff Responsibilities

Post	Responsibilities
• Consultant in Infectious Diseases or Genitourinary Medicine • Registrar in Infectious Diseases • Lead Pharmacist HIV & Hepatitis C • Clinical Nurse Specialist in HIV	• Follow the GUIDELINE for injectable cabotegravir and rilpivirine for adults living with HIV-1: prescribe, administer, monitor, or advise patients on injectable cabotegravir and rilpivirine as appropriate to role and competencies. • Where local and national guidance changes, highlight and contribute to the update/s required to the current version of the GUIDELINE for injectable cabotegravir and rilpivirine for adults living with HIV-1. • Offer potentially eligible adult patients living with HIV-1 ART with injectable cabotegravir and rilpivirine. Outline the risks and benefits of injectable cabotegravir and rilpivirine to this patient group. • Assess the suitability of giving potentially eligible adult patients living with HIV-1 injectable cabotegravir and rilpivirine in the local HIV MDT. Provide eligible patients information on injectable cabotegravir and rilpivirine when initiating therapy and throughout treatment. • Refer patients no longer suitable for injectable cabotegravir and rilpivirine e.g. due to inability to attend scheduled appointments back to the local HIV MDT for review of the ongoing treatment plan. • Medical and Non-medical prescribers (working within your prescribing competence and professional standards guidance): prescribe eligible adult patients living with HIV-1 injectable cabotegravir and rilpivirine (and where indicated oral cabotegravir and rilpivirine as lead-in or bridging therapy).

1. Identify and Consent Patients Eligible for Injectable ART

1.1 Patients can be considered for injectable ART where the following criteria are met:

- The patient faces significant challenge to taking daily oral ART,
- The patient is compliant with their current ART and has been virologically suppressed to <50 copies/ml for 6 months or more,
- The patient does not have a history of virological failure or unplanned treatment interruption on NNRTI or INSTI containing ART,
- The patient does not have a history of INSTI monotherapy,
- The patient has a BMI <30kg/m^2 and/or non-A1/6 subtype if baseline resistance is unavailable (having ONE of these features present DOES NOT contraindicate injectable ART, having BOTH of these features present DOES contraindicate eligibility for injectable ART),
- The patient can commit to 2 monthly clinic attendance for injectable ART,
- The patient understands the risk of virological failure and resistance with injectable ART despite complete adherence and the potential implications for U=U (undetectable = untransmittable),
- The patient does not require a tenofovir containing regimen for the treatment or prevention of Hepatitis B.

Explain the reasons to patients who do not meet the criteria above, for their non-eligibility for injectable ART.

1.2 Offer potentially eligible patients' literature about injectable ART. For example:
- https://www.bhiva.org/file/6356671bcbecd/LA-CAB-RPV-for-ART-NTS.pdf
- https://hivpa.org/wp-content/uploads/2023/06/Cabotegravir-and-Rilpivirine-LA-ART-HIVPA-leaflet.doc.pdf

1.3 See Appendix 1. For patients identified as potentially eligible for injectable ART complete the WAHNHST HIV clinics injectable cabotegravir/rilpivirine MDT referral form where their suitability will be assessed at the next WAHNHST HIV MDT (held on the first Wednesday of each calendar month).

1.4 Complete the Blueteq High-Cost drug form for patients approved to receive injectable ART by the HIV MDT. https://www.blueteq-secure.co.uk/Trust/default.aspx

1.5 See Appendix 2. Prior to commencing injectable ART, complete the patient consent form for patients approved to receive injectable ART by the HIV MDT.

1.6 Provide the patient with the scheduled dates of their first 4 months of appointments for injectable ART (includes appointments for optional one-month oral lead-in therapy, month 1 and 2 initiation injections, month 4 continuation injections).

2. Oral 'Lead-in' Therapy

2.1 Patients eligible for injectable ART can either go direct to injectable ART or receive oral lead-in therapy prior to commencing injectable ART. Oral lead-in therapy offers the opportunity to assess tolerability of both drugs and check maintenance of virological suppression prior to injectable cabotegravir/rilpivirine. The option of direct to injection or oral lead-in therapy prior to injection will be agreed with the patient, clinician, and HIV MDT.

2.2 Where oral lead-in therapy is used prescribe the following on a pink outpatient hospital prescription:
- **30 x Rilpivirine 25mg tablets** **25mg Once Daily for 1 month**
  Patient Information Leaflet HERE SPC HERE – counsel patient on food requirements
- **30 x Cabotegravir 30mg tablets** **30mg Once Daily for 1 month**
  Patient Information Leaflet and SPC HERE

2.3 Counsel the patient on how to take cabotegravir and rilpivirine, including the importance of managing the food requirements with rilpivirine. Supply supporting patient information as appropriate. Also note drug interactions differ between oral and injectable cabotegravir and rilpivirine. Seek advice where needed.

2.4 Record in the patient notes the date the patient will take their first dose of oral lead-in therapy**.** Advise the patient not to take any other ART on the day that oral lead-in therapy commences (i.e. the patient's prior regular oral ART regimen should stop after taking the previous day's dose/s).

2.5 Book an appointment for the patient to return to clinic for tolerability check and repeat viral load approximately 21 days after starting oral lead-in therapy **AND** book a second appointment 28-30 days after commencing oral lead-in therapy for the patient to attend to receive the first dose of injectable cabotegravir and rilpivirine (initiation phase: month 1 injection).

2.6 Check the viral load result before the patient attends for their first (month 1) initiation injections. If the viral load is no longer suppressed the patient should not receive injectable ART. They should continue oral lead-in therapy for a further month (defined as 28-30 days) and await the viral load to be fully supressed before proceeding to the first (month 1) initiation injections. If the viral load is not suppressed after a further month of oral lead-in

therapy, refer the patient back to the HIV MDT for reassessment of their ART treatment plan.

2.7 If the patient reports any adverse effects from either medication during oral lead-in therapy, these should be discussed with the doctor/pharmacist before deciding whether the patient should continue with this regimen. Complete a Yellow Card report for the adverse effect reported regardless of whether the patient is to continue or not.

Oral 'Lead-in' Therapy (Optional)	Initiation Phase		Continuation Phase
Duration: 28-30 days	**Month 1**	**Month 2**	**Month 4**
Commence oral cabotegravir/ rilpivirine	1st dose of injectable cabotegravir/ rilpivirine	2nd dose of injectable cabotegravir/ rilpivirine	3rd & subsequent doses of injectable cabotegravir/ rilpivirine **To be given every 2 months thereafter**

3. Injectable Cabotegravir and Rilpivirine: Initiation Phase

3.1 Where oral lead-in therapy has been prescribed. The patient should attend the clinic 28-30 days after commencing oral lead-in therapy for the first doses (month 1: initiation phase) of injectable cabotegravir and rilpivirine. Advise the patient they will take their final doses of oral cabotegravir and rilpivirine on the same day as their first injections.

3.2 Where the patient is to receive direct to injection. The patient should attend the clinic for the first doses (month 1: initiation phase) of injectable cabotegravir and rilpivirine. Advise the patient they will take their final dose/s of their existing oral ART therapy on the same day as their first injections.

3.3 Month 1 initiation injections, prescribe on a pink hospital outpatient prescription:

- **1 x Rilpivirine 900mg injection**
  900mg (3ml) month 1 initiation injection, 1 x stat dose
- **1 x Cabotegravir 600mg injection**
  600mg (3ml) month 1 initiation injection, 1 x stat dose

3.4 Month 2 initiation injections, prescribe on a pink hospital outpatient prescription:

- **1 x Rilpivirine 900mg injection**
  900mg (3ml) month 2 initiation injection, 1 x stat dose
- **1 x Cabotegravir 600mg injection**
  600mg (3ml) month 2 initiation injection, 1 x stat dose

3.5 Rilpivirine injection must be removed from the fridge at least 15 minutes before administration to allow it to reach room temperature. Once the vial of rilpivirine has been removed from the refrigerator, it cannot be re-refrigerated and must be used within 6 hours. Cabotegravir injection does not require refrigeration or have any special storage conditions. Complete steps 3.6 to 3.17 for the administration of both cabotegravir and rilpivirine injections.

3.6 Remove both vials from the packaging and inspect both cabotegravir and rilpivirine vials for any foreign matter. If all clear, shake the vials vigorously for 10 seconds to check the suspension is uniformly mixed.

3.7 Remove the vial caps and wipe the rubber seals with the alcohol swab provided.

3.8 Aseptically open the adapter provided in the packaging and press down firmly on top of the rubber seal until it clicks into place.

3.9 Using the syringe provided, draw up 1ml air, screw the syringe onto the adapter and press the plunger down to push the air into the vial.

3.10 Invert the syringe and vial and slowly withdraw all the liquid. Once finished, unscrew the syringe from the vial adapter keeping the syringe upright. Note once the drug has been drawn into the syringe the injections must be used within 2 hours and storage temperature must not exceed 25^{o}C.

3.11 Attach the needle provided to the syringe and remove the packaging. Press the syringe plunger down to the 3ml line to remove any air bubbles/extra fluid in the chamber. Note consider the BMI of the patient and use clinical judgement to assess whether the length of needle included is sufficient to reach the gluteal muscle.

3.12 Select the injection site. Note rilpivirine and cabotegravir injections are for **gluteal intramuscular injection only** (do not inject intravenously) and must be injected into different administration sites. The order of injection administration is not important, it is suggested to inject cabotegravir into the left buttock and rilpivirine into the right buttock. Use either the **ventrogluteal area (recommended)** or dorsogluteal area (upper outer quadrant).

3.13 Inject intramuscularly using the Z-Track injection technique to reduce medication leakage. To do this, drag the skin by 2.5cm and hold in place for the injection.

3.14 Remove the needle guard, insert the needle to its full depth and slowly push the plunger down, ensuring the syringe is empty before withdrawing and releasing the skin. Safely discard the needle and syringe.

3.15 Apply firm pressure to the injection site using cotton wool or gauze. **Do not massage the area.**

3.16 Observe the patient for 10 minutes after receiving both injections for any post-injection reaction/s.

3.17 Document administration of the injections in the patients notes.

3.18 Ensure an appointment for the patient is booked to return to the clinic in one month for the next month 2 initiation phase loading dose injections and viral load blood test. This is the next Target Treatment Date (TTD).

3.19 Check the viral load result after each clinic attendance (viral load blood samples should be taken at every visit prior to receiving the next dose). If the viral load remains <20 copies/ml the patient may receive the next dose of injectable cabotegravir and rilpivirine. If the viral load is >20 copies/ml, discuss the result with the HIV MDT before continuing to administer the next dose.

3.20 Once the two (month 1 and 2) initiation phase injection doses are given the patient should commence ‘continuation phase’ injections. Check an appointment has been booked for the patient to attend in 2 months’ time for their month 4 continuation injections (i.e. 4 months after the date oral lead-in therapy was commenced or 3 months after the first month 1 initiation phase injection). This will be their new TTD.

4. Injectable Cabotegravir and Rilpivirine: Continuation Phase

4.1 Month 4 continuation injections onwards, prescribe on a pink hospital outpatient prescription:

- **1 x Rilpivirine 900mg injection**
  900mg (3ml) continuation injection, 1 x stat dose every 2 months
- **1 x Cabotegravir 600mg injection**
  600mg (3ml) continuation injection, 1 x stat dose every 2 months

4.2 Repeat steps 3.5 to 3.17.

4.3 Check the viral load result after each clinic attendance (viral load blood samples should be taken at every visit prior to receiving the next dose). If the viral load remains <20 copies/ml the patient may receive the next dose of injectable cabotegravir and rilpivirine. If the viral load is >20 copies/ml, discuss the result with the HIV MDT before continuing to administer the next dose.

4.4 Book an appointment for the patient to attend in 2 months' time for their next continuation injections This will be their new TTD.

5. Managing Missed Appointments for TTD and When to Commence Oral 'Bridging-Therapy'

5.1 Patients should be strongly encouraged to attend the clinic on their TTD every time to ensure they have the highest chance of remaining virally supressed and to reduce the risks of developing drug resistance and as agreed when they completed the patient consent form for patients approved to receive injectable ART by the HIV MDT (Appendix 2).

5.2 If a patient is unable to attend an appointment (i.e. their next TTD) cabotegravir and rilpivirine injections have a flexible dosing window meaning doses can be given up to 7 days before or after the TTD. Doses however cannot be given more than 7 days prior to the TTD. If within the +/- 7-day flexible dosing window offer the patient an alternative appointment to receive their injections.

5.3 If the patient cannot attend or be scheduled within the +/- 7-day flexible dosing window, they should be prescribed oral cabotegravir and rilpivirine 'bridging therapy' and booked a suitable appointment for their new TTD.

5.4 Where oral bridging therapy is required prescribe the following on a pink outpatient hospital prescription:

- **30 x Rilpivirine 25mg tablets** **25mg Once Daily for 1 month**
  Patient Information Leaflet HERE SPC HERE – counsel patient on food requirements
- **30 x Cabotegravir 30mg tablets** **30mg Once Daily for 1 month**
  Patient Information Leaflet and SPC HERE

Note further supplies of oral bridging therapy may be required (see table below). Note drug interactions differ between oral and injectable cabotegravir and rilpivirine. Seek advice where needed.

5.5 Missed injection appointments should be managed as outlined in the table below and their new TTD appointment scheduled accordingly. The viral load must be checked at every rescheduled appointment.

Missed Injection Visit	Time Since Last injections	
Month 2 Initiation Injections	**< 2 Months**	**> 2 Months**
Initiation phase max. duration oral bridging therapy = 2 months	Give Month 2 initiation injections ASAP and then proceed with 2 monthly continuation injections	Give Month 2 initiation injections ASAP, administer the next injections one month later and then proceed with 2 monthly continuation injections
Month 4 Continuation Injections onwards	**< 3 Months**	**> 3 Months**
Continuation phase max. duration oral bridging therapy = 3 months	Give 2 monthly continuation injections ASAP and then continue with 2 monthly continuation injections	Give 2 monthly continuation injections ASAP, administer the next injections one month later and then continue with 2 monthly continuation injections

5.6 Any patient accessing oral bridging therapy for one month or longer and/or missing two or more TTD appointments must be reassessed for suitability for injectable ART by the HIV MDT.

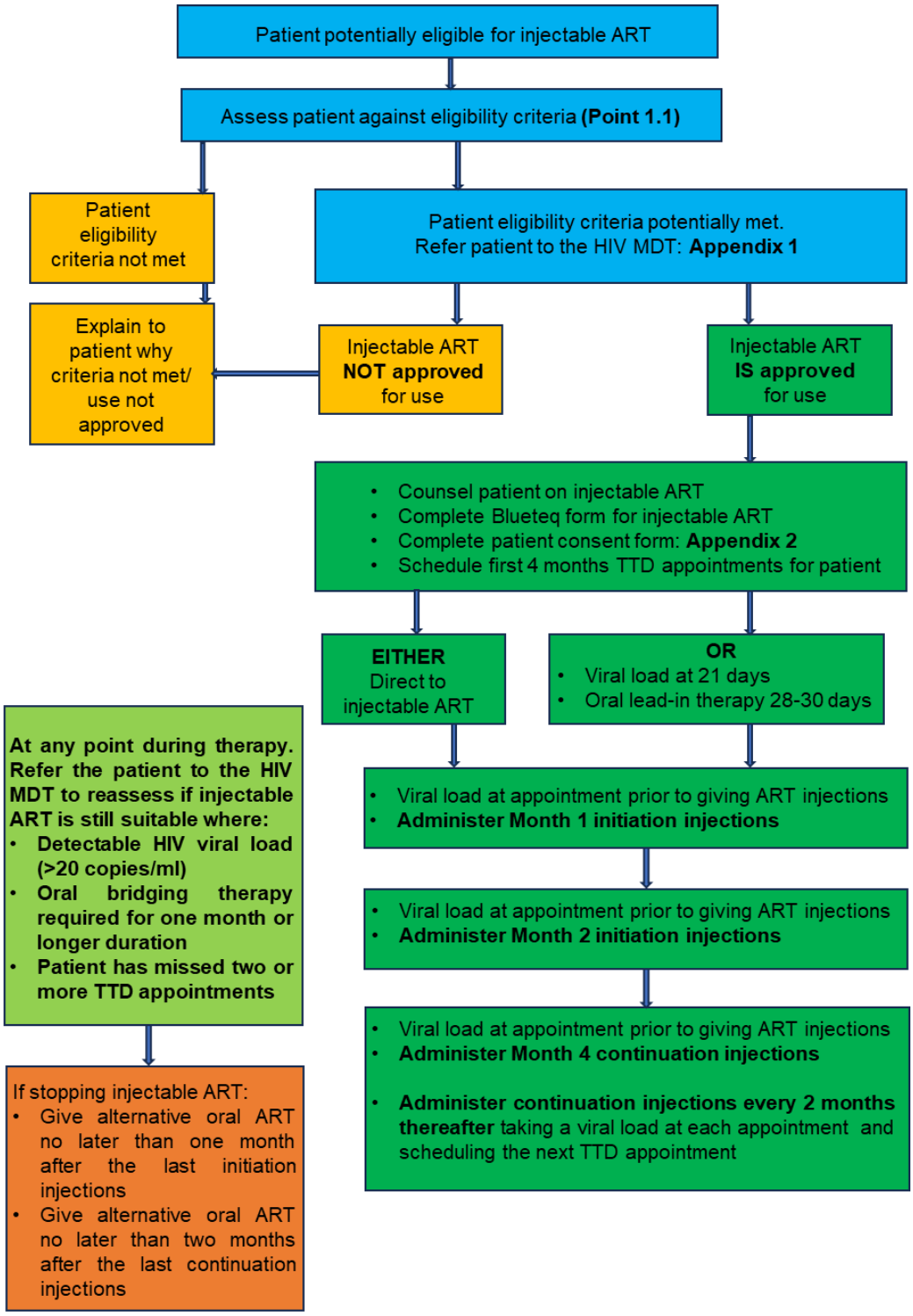
6. Stopping Injectable ART and Detectable Viraemia

6.1 If injectable ART is discontinued, it is essential to start alternative ART no later than two months after the final injection if in the continuation phase of treatment or no later than one month after the final injection if in the initiation phase of treatment, to minimise the chance of developing drug resistance.

6.2 Every patient stopping injectable ART must be referred to the HIV MDT for discussion of the ongoing treatment plan.

6.3 Every patient with a detectable viral load (>20 copies/ml) at any point during injectable ART must also be referred to the HIV MDT for discussion of the ongoing treatment plan. A viral load must be taken at every appointment where injectable ART is administered and 21 days after commencing oral lead-in therapy.

7. GUIDELINE summary flow-chart



Monitoring

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the Policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
	These are the 'key' parts of the process that we are relying on to manage risk. We may not be able to monitor every part of the process, but we MUST monitor the key elements, otherwise we won't know whether we are keeping patients, visitors and/or staff safe.	What are we going to do to make sure the key parts of the process we have identified are being followed? (Some techniques to consider are; audits, spot-checks, analysis of incident trends, monitoring of attendance at training.)	Be realistic. Set achievable frequencies. Use terms such as '10 times a year' instead of 'monthly'.	Who is responsible for the check? Is it listed in the 'duties' section of the Policy? Is it in the job description?	Who will receive the monitoring results? Where this is a committee the committee's specific responsibility for monitoring the process must be described within its terms of reference.	Use terms such as '10 times a year' instead of 'monthly'.
Point 1.1 – P 4 App 1 – P 13-15 App 2 – P 16	Monitor which patients are identified and consented for treatment with injectable cabotegravir/ rilpivirine	Audit	Annual	Dr Mark Roberts Lead Consultant in Infectious Disease to assign	Infectious Diseases Directorate Meeting	Annual
Section 6 – P 9 Section 7 – P 10	Monitor those patients whom are reviewed by MDT due to viraemia during treatment with injectable cabotegravir/ rilpivirine, recurrent oral bridging therapy and/or stopping injectable cabotegravir/rilpivirine	Audit	Annual	Dr Mark Roberts Lead Consultant in Infectious Disease to assign	Infectious Diseases Directorate Meeting	Annual

References

Internal Documents:	*Reference:*
• WAHNHST: Medicines Policy (Policy on the Purchasing, Prescribing, Supply, Storage, Administration and Control of Medicines) – July 2020	index
• WAHNHST: Policy and Procedures for the Prescribing and Administration of Injectable Medicines – December 2021	index
• WAHNHST: Worcestershire Acute Hospitals Non-medical Prescribing Policy – September 2023	index
External Documents:	
• NICE Technology Appraisal 757: Cabotegravir with Rilpivirine for treating HIV-1 – January 2022	https://www.nice.org.uk/guidance/ta757
• British HIV Association: Antiretroviral Treatment for Adults Living with HIV-1 Infection – 2022 (Update 2023)	https://www.bhiva.org/guidelines
• HIV Clinical Reference Group: Best Practice in HIV Prescribing and Multidisciplinary Teams – October 2019	https://www.england.nhs.uk/commissioning/spec-services/npc-crg/blood-and-infection-group-f/hiv/
• HIV Pharmacy Association: Patient Information Leaflet for Cabotegravir and Rilpivirine – June 2023	https://hivpa.org/patient-information-leaflets-pils/
• Summary of Product Characteristics for Cabotegravir and Rilpivirine	https://www.medicines.org.uk/emc#gref
• British National Formulary Online	https://bnf.nice.org.uk/

Contribution List

Contribution List

This key document has been circulated to the following individuals for consultation;

Designation
Rachael Leese: Lead Pharmacist HIV & Hepatitis C
Dr Mark Roberts: Lead Consultant in Infectious Diseases
Caroline Lister: Directorate Manager Infectious Diseases
Georgina Darby: Matron BBV Team
Dr Louise Seppings: Consultant in Genitourinary Medicine
Dr Jacob Martins-Okonsukwa: Consultant in Genitourinary Medicine
Dr Katelyn Monsell: Registrar in Infectious Diseases
Samantha Green: HIV Clinical Nurse Specialist
Melinda Kemp: HIV Clinic Nurse Specialist
Anita Griffiths: HIV Clinical Nurse Specialist
Joanne Maguire: HIV Dietitian
Jayne Andrews: Healthcare Assistant BBV Team
Joanne Dando: Healthcare Assistant HIV Team

This key document has been circulated to the chair(s) of the following committee's / groups for comments;

Committee
Infectious Diseases Directorate Meeting 19.02.24
Divisional Management Board 21.05.24
Medicines Safety Committee 10.06.24

Appendix 1: WAHNHST HIV Clinics Injectable Cabotegravir/Rilpivirine MDT Form

WAHNHST HIV Clinics Injectable Cabotegravir/Rilpivirine MDT Form

Patient Name: DOB:	Address:
NHS Number: Hospital Number:	GP Surgery:

Viral load results (last 3 results):		
Viral load	Results:	Date:
Viral load	Results:	Date:
Viral load	Results:	Date:

	Additional patient factors:	
ART Resistance		Date:
HIV Subtype		Date:
BMI	Height:_____ Weight: _____ BMI: _____	Date:
Hepatitis B status		Date:

Current ART:

_____

Date next prescription due:

_____

Allergies:

_____

Prior ART regimens:

_____

Other medication taken (to include GP, OTC, herbal and illicit use):

_____

_____

_____

Worcestershire Acute Hospitals NHS Trust

WAHNHST HIV Clinics Injectable Cabotegravir/Rilpivirine MDT Form

Patient Name: DOB:	NHS Number: Hospital Number:

• Does the patient face significant challenge to taking daily oral ART? *(Please document the nature of challenges faced in the MDT notes)*	Yes/ No
• Has the patient been virologically suppressed to <50 copies/ml for 6 months or more?	Yes/ No
• Does the patient have known or suspected NNRTI or INSTI resistance? • Does the patient have a history of virological failure or unplanned treatment interruption on NNRTI or INSTI containing ART? • Does the patient have a history of INSTI monotherapy?	Yes/ No Yes/ No Yes/No
• Does the patient have a BMI <30kg/m^2 • Does the patient have non-A1/6 subtype if baseline resistance is unavailable?	Yes/ No Yes/ No
• Can the patient commit to 2 monthly attendance for injectable ART? *(Please document any concerns in the MDT notes)* • Has the risk of virological failure and resistance despite complete adherence and the potential implications for U=U been explained to the patient?	Yes/ No Yes/ No
• Does the patient require a tenofovir containing regimen for the treatment or prevention of Hepatitis B?	Yes/ No
• Has the patient been prescribed injectable cabotegravir/rilpivirine as part of a clinical trial or compassionate use access scheme?	Yes/ No

Worcestershire Acute Hospitals NHS Trust

WAHNHST HIV Clinics Injectable Cabotegravir/Rilpivirine MDT Form

Patient Name: DOB:	NHS Number: Hospital Number:

MDT Date: _____

Team Members present at MDT (tick and document):

- Infectious Diseases Consultant: Dr. Mark Roberts
- Sexual Health Consultant: Dr. Jacob Martins Okonsukwa
- Sexual Health Consultant: Dr. Louise Seppings
- HIV CNS: Samantha Green
- HIV CNS: Melinda Kemp
- HIV Dietitian: Joanne Maguire
- HIV Pharmacist: Rachael Leese
- Other Team Members (name and job role):

_____
_____
_____

MDT Notes:

Injectable Cabotegravir/Rilpivirine Use Approved: Yes/No

Where one of the following factors are identified only *ONE* exists for the patient (baseline rilpivirine polymorphisms/ BMI >30kg/m^2 or subtype A1/6): Yes/No/NA

Blueteq ID (if approved): _____

Print Name: _____ **Signature:** _____

Position: _____ **Date:** _____

Appendix 2: WAHNHST HIV Clinics Injectable Cabotegravir/Rilpivirine Patient Consent Form for Patients Approved to Receive Injectable ART by the HIV MDT

WAHNHST HIV Clinics Injectable Cabotegravir/Rilpivirine Patient Consent Form for Patients Approved to Receive Injectable ART by the HIV MDT

Patient Name: DOB:	NHS Number: Hospital Number:

The HIV MDT has assessed that the patient meets the eligibility criteria for injectable ART. The patient has been counselled on injectable ART and provided with supporting information where appropriate. • Does the patient consent to receiving injectable ART?	Yes/ No
The patient will be required to attend monthly appointments for the initiation phase and 2 monthly appointments during the continuation phase of treatment. Injectable ART has a short +/- 7-day flexible dosing window either side of injection due dates. • Does the patient understand the importance of attending scheduled appointments? • Does the patient understand that the decision to offer injectable ART will be reviewed by the HIV MDT where scheduled appointments are missed and/or oral cabotegravir/rilpivirine bridging therapy is prescribed?	Yes/ No Yes/ No
In clinical trials, about 1 in 70 people on 2-monthly injectable cabotegravir/rilpivirine experienced viral rebound (detectable viral load) at year 1, and 1 in 60 at year 2, despite 100% adherence, and most of those also developed resistance to one or both drugs. • Does the patient understand the greater risk of virological failure of injectable ART versus standard oral therapy? • Does the patient understand that consequently, despite 100% adherence U = U (undetectable = untransmittable) may not be maintained on injectable ART? • Does the patient understand that the decision to offer injectable ART will be reviewed where the viral load is detectable and/or drug resistance develops?	Yes/ No Yes/ No Yes/No

Patient Signature: _____ **Date:** _____

HCPs Name:_____ **Signature:** _____

Position: _____ **Date:** _____

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page;

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust	X	Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	**Dr Mark Roberts: Lead Consultant in Infectious Diseases**

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
	Rachael Leese	**Lead Pharmacist HIV & Hepatitis C**	**r.leese@nhs.net**
Date assessment completed	**04.06.24**		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title: Guideline for the Use of Injectable Cabotegravir and Rilpivirine in Adults Living with HIV-1**			
What is the aim, purpose and/or intended outcomes of this Activity?	Guideline to support the use of injectable cabotegravir and rilpivirine as a treatment option for adults living with HIV-1 treated via the WAHNHST HIV service			
Who will be affected by the development & implementation of this activity?	X❑ X❑ X❑ ❑	Service User Patient Carers Visitors	X❑ ❑ ❑ ❑	Staff Communities Other _____
Is this:	❑ Review of an existing activity X❑ New activity			

	❑ Planning to withdraw or reduce a service, activity or presence?
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	• WAHNHST HIV Team • NICE Technology Appraisal 757: Cabotegravir with Rilpivirine for treating HIV-1 – January 2022 https://www.nice.org.uk/guidance/ta757 • British HIV Association: Antiretroviral Treatment for Adults Living with HIV-1 Infection – 2022 (Update 2023) https://www.bhiva.org/guidelines
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	Guideline distributed to the Infectious Diseases Directorate, Divisional Management Board and Medicines Safety Committee for consideration and local approval
Summary of relevant findings	Approved Infectious Disease Directorate 19.02.24. Approved Divisional Management Board 21.05.24. Medicines Safety Committee Agenda item 10.06.24

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age	X		X	Positive: new treatment option for adults living with HIV-1 treated by WAHNHST Negative: those <18 years not eligible. Increased clinic attendance (from standard 2 x per year) may not be feasible for some patients
Disability	X		X	Positive: new treatment option for adults living with HIV-1 treated by WAHNHST Negative: increased clinic attendance (from standard 2 x per year) may not be feasible for some patients
Gender Reassignment	X		X	Positive: new treatment option for adults living with HIV-1 treated by WAHNHST Negative: increased clinic attendance (from standard 2 x per year) may not be feasible for some patients
Marriage & Civil Partnerships	X		X	Positive: new treatment option for adults living with HIV-1 treated by WAHNHST Negative: increased clinic attendance (from standard 2 x per year) may not be feasible for some patients

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Pregnancy & Maternity			X	Negative: in the absence of safety data not a treatment option in pregnant women living with HIV-1
Race including Traveling Communities	X		X	Positive: new treatment option for adults living with HIV-1 treated by WAHNHST Negative: increased clinic attendance (from standard 2 x per year) may not be feasible for some patients
Religion & Belief	X		X	Positive: new treatment option for adults living with HIV-1 treated by WAHNHST Negative: increased clinic attendance (from standard 2 x per year) may not be feasible for some patients
Sex	X		X	Positive: new treatment option for adults living with HIV-1 treated by WAHNHST Negative: increased clinic attendance (from standard 2 x per year) may not be feasible for some patients
Sexual Orientation	X		X	Positive: new treatment option for adults living with HIV-1 treated by WAHNHST Negative: increased clinic attendance (from standard 2 x per year) may not be feasible for some patients
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)	X		X	Positive: new treatment option for adults living with HIV-1 treated by WAHNHST Negative: increased clinic attendance (from standard 2 x per year) may not be feasible for some patients
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)	X		X	Positive: new treatment option for adults living with HIV-1 treated by WAHNHST Negative: increased clinic attendance (from standard 2 x per year) may not be feasible for some patients

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate	Who will lead on the action?	Timeframe

		negative impact		
	Increased clinic attendance (from standard 2 x per year) may not be feasible/practical for some patients	Explore options to facilitate increased clinic attendance e.g. hospital transport	**Dr. Mark Roberts to assign as Lead Consultant in Infectious Diseases**	**December 2024**
	In the absence of safety data not a treatment option in pregnant women living with HIV-1	Review this as a treatment option in pregnant women living with HIV-1 as safety data becomes available to support use	**Dr. Mark Roberts to assign as Lead Consultant in Infectious Diseases**	**Ongoing**
How will you monitor these actions?	**Audit of patients whom have commenced treatment with injectable cabotegravir/ rilpivirine to assess characteristics of those receiving and/or potential barriers to accessing this treatment option**			
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)	**June 2025**			

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	Rachael Leese, Lead Pharmacist HIV & Hepatitis C
Date signed	10.06.24
Comments:	

Signature of person the Leader Person for this activity	Dr. Mark Roberts, Lead Consultant in Infectious Diseases
Date signed	10.06.24
Comments:	

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	Yes
2.	Does the implementation of this document require additional revenue	Yes
3.	Does the implementation of this document require additional manpower	Yes
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments: Please refer to the following documents re: cost effectiveness analysis and potential service impacts: • NICE Technology Appraisal 757: Cabotegravir with Rilpivirine for treating HIV-1 – January 2022 https://www.nice.org.uk/guidance/ta757 • British HIV Association: Antiretroviral Treatment for Adults Living with HIV-1 Infection – 2022 (Update 2023) https://www.bhiva.org/guidelines	See references opposite

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval.