Buvidal (buprenorphine prolonged-release injection)

Considerations for opioid substitution treatment use in community settings and secure environments in England

Regional Medicines Optimisation Committee (RMOC)

April 2021

Version 1.0

DOCUMENT CONTROL

Document location

Copies of this document can be obtained from https://www.sps.nhs.uk/

Revision history

Revision date	Actioned by	Summary of changes	Version
September 2020	NELCSU	Prepared by the NEL Commissioning Support Unit for consideration by RMOC South	V1
September 2020	NELCSU	Updated to reflect comments made by RMOC South members, for national consultation with RMOC members, APCs and	V2
January 2021	NELCSU	Updated to reflect comments by RMOC members, APCs and Pharmaceutical company following national consultation	V3
February 2021	NELCSU	Amended post RMOC South January 2021 meeting	V4.0
April 2021	SWMI	V4.0 to working version 1 for NHSE approval	WV1

This RMOC advice has been supported by work undertaken by the Commissioning Support Unit

Approvals

This document must be approved by the following before distribution:

Name	Date of issue	Version
RMOC South	February 2021	V4.0
NHSEI	April 2021	Final V1.0 Publishing Approval Reference: PAR511

Document Review Date: April 2022

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Scope of guidance

At the time of writing, Buvidal is the only prolonged-release buprenorphine injectable product available in the UK. At the time of writing, National Institute for Health and Care Excellence (NICE) and Department of Health and Social Care guidelines have not yet included prolonged-release buprenorphine in their treatment pathways.

This review aims to support commissioners and their system partners in local decision making on considerations for introducing Buvidal to their services and how they choose to deliver this. It aims to identify patient cohorts who may benefit from Buvidal and helps them understand the potential clinical and practical challenges involved. This guidance will focus on Buvidal in England, but it is recognised that the general principles may be applied to other future buprenorphine injectable products. This guidance is intended for use by substance misuse service providers (SMSPs) in all settings, commissioners, community pharmacies, mental health trusts, community trusts and acute trusts in England. For this guidance, SMSPs should be interpreted as providers within community and Health and Justice settings (such as prisons, immigration removal centres, children and young people secure estates). It was developed by a range of stakeholders (available upon request) from various sectors in England with expertise in substance misuse.

Key messages

- Prolonged-release buprenorphine, Buvidal which is given as weekly or monthly injections is a suitable opioid substitution therapy (OST) option for specific cohorts of opioid dependent service users.
- Careful considerations around patient selection needs to be made because prolonged-release buprenorphine may not be suitable for all opioid dependent users.
- Buvidal is more expensive compared to other forms of OST, with possible costs associated with administration.
- However, prolonged-release buprenorphine may address an unmet clinical need in specific cohorts of service users which may support them into gaining stability and a ‘drug free’ life, for example via undisrupted employment or education.
- Continuity of care may be an issue because Buvidal is not routinely commissioned throughout England.
- There are practicalities around procurement, storage, administration, staffing and training which need to be considered when introducing prolonged-release buprenorphine into local substance misuse pathways. It requires a system-wide approach to ensure continuity of care for service users.
- SMSPs and commissioners are advised to use the criteria outlined in this document to identify specific cohorts of service users who may benefit most from this treatment, whilst being mindful of the considerations associated with implementing Buvidal safely in local substance misuse pathways.

1. What is Buvidal?

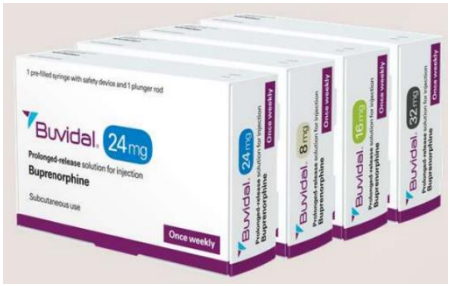
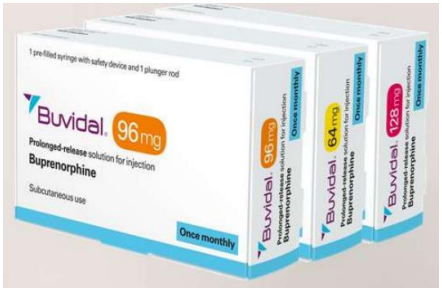
Buvidal is a prolonged-release subcutaneous injection containing buprenorphine. It is available in 2 different formulations which are administered at either **weekly** (8mg, 16mg, 24mg, 32mg) or **monthly** (64mg, 96mg, 128mg) intervals. (1,2)

It is licensed in adults and adolescents aged 16 years or over for the treatment of opioid dependence within a framework of medical, social, and psychological treatment. (1,2)

This is currently the only form of opioid substitution therapy (OST) available in the UK which does not require daily or alternate days dosing.

Table 1 highlights the differences in outer packaging between the strengths and formulations available for Buvidal.

Table 1. Outer packaging differences of weekly and monthly Buvidal injections

Buvidal formulation	**Weekly**	**Monthly**
Strengths available	8mg, 16mg, 24mg, 32mg	64mg, 96mg, 128mg
Outer packaging images (3)		
Outer packaging differences	**Purple** themed boxes "Once weekly" highlighted in **purple box** at bottom right hand corner of the boxes Different strengths presented in different colours	**Blue** themed boxes "Once monthly" highlighted in **blue box** at bottom right hand corner of the boxes Different strengths presented in different colours

To avoid mis-selection during dispensing, it is advised to store the monthly and weekly injections separately (for example storing the weekly product at a different shelf from the monthly product).

2. Administration issues

Buvidal is intended to be administered subcutaneously only. It should be injected slowly and completely into the subcutaneous tissue of different areas (buttock, thigh, abdomen, or upper arm), provided there is enough subcutaneous tissue. Each area can have multiple injection sites. Injection sites should be rotated for both weekly and monthly injections. A minimum of 8 weeks should be left before re-injecting a previously used injection site with the weekly dose. There is no clinical data supporting reinjection of the monthly dose into the same site. The decision to reinject at the same site should be guided by the registered healthcare professional's clinical judgement. The administered dose should be as a single injection and not divided. The dose must not be administered intravenously intramuscularly or intradermally (into the skin). (1,2)

Intravenous injection would present a risk of serious harm as Buvidal forms a solid mass upon contact with body fluids, which potentially could cause blood vessel injury, occlusion, or thromboembolic events. (1,2)

The needle shield of the safety syringe may contain rubber latex that may cause allergic reactions in latex-sensitive individuals. (1,2)

Unlike other forms of OST, Buvidal should **only be administered by registered healthcare professionals (HCP)**. This prevents drug diversion and the risk of injecting incorrectly. **According to the summary of product characteristics (SPC), service users must not have Buvidal (even as a dispensed medicine) in their possession to take home for self-administration or for a registered HCP to administer**. (1,2)

3. Duration of effects

The terminal plasma half-life of single doses of Buvidal are longer than the sublingual[1] or supralingual[2] products: (4)

- weekly Buvidal: 3 to 5 days
- monthly Buvidal: 19 to 25 days

According to model simulations and clinical experience, buprenorphine plasma concentrations decline slowly with time due to its prolonged release properties. It can remain in the system for extended periods following the last injection (weekly Buvidal- up to 3 weeks, monthly Buvidal– up to 12 weeks). This may cause delayed experience of side effects, delayed emergence of withdrawal symptoms, possibly impact management of drug-drug interactions and switching to alternative OST. It may also result in delayed reduction of tolerance to opioids and be protective against overdose following resumption of heroin or other opioid use. (1,2,4)

4. Undesirable effects

The side effects reported for Buvidal are similar to sublingual or supralingual buprenorphine, with addition of injection-related side effects (e.g. injection site pain, pruritus and erythema pain). (1,2) The summary of product characteristics (SPC) has the full details. As with all adverse events, healthcare professionals and patients are asked to report serious suspected adverse reactions via the Yellow Card Scheme.

The benefits and risks, from operational and clinical perspectives of using Buvidal over conventional oral OST that would support local formulary considerations are summarised in Table 2.

[1] Sublingual is a route of administration where medication is taken **under** the tongue.
[2] Supralingual is a route of administration where medication is taken **on** the tongue. This normally applies to oral lyophillisate products such as Espranor.

Table 2. Benefits and risks (clinical and operational) of using Buvidal over oral OST

Benefits	Risks
- Convenient, removes the need to attend regular OST supervision/pick up if this would be considered necessary - Possibly improves adherence and concordance to treatment plan in community due to reduced need for daily pick ups - Reduces pressure on supervised consumption services in both community and secure environments - Reduces need for service users to attend daily OST immediately following release from prison - Avoids stigma attached to daily supervised consumption - Useful in settings where drug diversion or safe medication storage by the service user is an issue - Possibly facilitates the person to go back into a 'drug free' life, gaining stability in terms of employment or education if service user maintains abstinence - Gives freedom to travel within UK and abroad without needing to take medications with them - Possibly reduces administrative burden costs associated with daily OST - Flexible administration timings with Buvidal (up to 1 week or 1 month pending on formulation) in the event the service user is unable to attend their scheduled appointment. Potentially reduces the need for dose re-titration compared to oral OST for missed doses. - Prolonged release profile offers more stability as opposed to daily peaks and troughs from daily oral OST	- Reduces contact time with healthcare professionals for OST, reduces potential opportunities to pick up underlying issues which may affect service user's general health. May require service redesign by SMSPs to be able to pick up these issues in a timely manner. - Risk of disengagement from other supportive interventions if service user chooses to only have medications but not engage with psychosocial element. A different approach (for example coincide injection appointments with therapy sessions) may be required for effective treatment delivery. - For unplanned prison releases or where immediate appointments cannot be made, service users must not be supplied with Buvidal to take home. They would rely on community GP or substance misuse service appointment to ensure next dose is given on time. Normally service users who are on oral OST could be issued with FP10MDA as a bridging supply. - In the event of polysubstance misuse or intoxication whilst on Buvidal, medical management may be more complex compared to oral OST due to its prolonged-release properties - Pain management (chronic or acute) may need to be managed differently due to its extended release profile - Daily doses of oral OST can be withheld if required. Buvidal will remain clinically active in the system after the last injection (weekly Buvidal- up to 3 weeks, monthly Buvidal– up to 12 weeks). This means that any intoxication during a month of treatment with Buvidal cannot be managed by withholding buprenorphine. This may also have implications for treatment needed in hospital - Potential lack of continuity of care if receiving provider does not offer Buvidal in their service - Access for weekly or monthly injections may not be as local to home or workplace as daily access via pharmacies - May not be suitable for needle-phobic service users - Additional training, including anaphylaxis training may be required for staff administering - Additional operational set up required to deliver prolonged-release buprenorphine safely on-site and in line with legislative framework, which may include Home Office licence for controlled drugs where stocks are held. This may be different in community services, community pharmacies and prison settings - Administration route is associated with more risks. Prolonged-release buprenorphine must be administered subcutaneously by a registered healthcare professional with close contact - Individual appointment times for injections may take longer for service users compared to oral dose supervision. In Health and Justice, service users may have to be accompanied to their appointment, wait before and after their appointments before they are accompanied back. This might impact more on their work or education compared to daily supervision. - Potential need for chaperone due to social embarrassment associated with some administration sites - Need to ensure adrenaline is available for anaphylaxis emergencies

5. Interaction with other medicinal products

There are no published interaction studies available with Buvidal, however the expected pharmacological drug interaction profile would be like sublingual or supralingual buprenorphine. (1,2)

Some of the notable drug interactions include: (1,2)

- Opioid analgesics (precipitated withdrawal, enhanced central nervous system (CNS) depression, serotonin syndrome with opioids which possess serotogenic properties)
- Opioid antagonists (precipitated withdrawal)
- Gabapentinoids, benzodiazepines (risk of respiratory depression)
- Alcohol and other central nervous depressants (e.g. sedative H1 antagonists, tricyclic antidepressants) (increase sedation)
- CYP3A4 inducers (decreased buprenorphine levels)
- CYP3A4 inhibitors (increased buprenorphine levels)
- Serotonergic medicinal products, such as MAO inhibitors, selective serotonin re-uptake inhibitors (SSRIs), serotonin norepinephrine re-uptake inhibitors (SNRIs) or tricyclic antidepressants (risk of serotonin syndrome)

Some of these medicines may be used with caution with concurrent Buvidal administration depending on clinical need. Due to its extended release properties, management of drug-drug interactions would require additional clinical monitoring and dose adjustments. Full details are available in the SPC.

6. Service user cohort who are likely to benefit from treatment

At the time of writing, National Institute for Health and Care Excellence (NICE) and Department of Health and Social Care guidelines have not yet included prolonged-release buprenorphine in their treatment pathways as the injectable product was licensed in the UK in November 2018. (5,6) NICE have published an evidence review on Buvidal (ES19) and recognised Buvidal may be beneficial in the following situations: (7)

- where there is a risk of diversion of opioid substitution medicines or concerns about the safety of medicines stored at home
- for service users who have difficulties adhering to daily supervised opioid substitution medication
- for service users in custodial settings, where the risk of diversion and time needed for supervised consumption currently leads to challenges in supplying supervised medicines safely

The Scottish Medicines Consortium recommended this formulation for service users whom methadone is not suitable and for whom the use of buprenorphine is considered appropriate. (8)

The All Wales Medicines Strategy Group recommended Buvidal as an option for use within NHS Wales for the treatment of opioid dependence within a framework of medical, social and psychological treatment in adults and adolescence aged 16 years and above. (9)

The decision to use prolonged-release buprenorphine over other OST will need to consider the service user's clinical circumstances, both clinician's and service user's preference as well as other

practicalities as outlined in Chapter 4 of Drug Misuse and Dependence: UK Guidelines on Clinical Management. (6)

There is currently insufficient clinical experience in the UK to suggest specific cohorts who may most benefit from this formulation. However, it is recognised that prolonged-release buprenorphine may be beneficial under the following circumstances:

6.1 Community settings

- Situations where there is a risk of diversion of opioid substitution medicines.
- Concerns about safety of medications storage at home (i.e. homeless, residential rehabilitation or supported housing, children or vulnerable adults at home, people subjected to domestic violence and need to move residence, people who are vulnerable to bullying and coercion).
- Difficulties attending daily or weekly supervised schedule at a pharmacy which impacts significantly in a negative way on their recovery. Monthly appointments would be more convenient for this cohort. For example, service users who:
    - Travel abroad
    - Have work or study commitments
    - Have mobility issues
    - Live in rural areas where access to community pharmacies will be difficult
- Service users who have highly complex lifestyles and unable to adhere with daily dosing schedules.
- Difficulties optimising OST with oral products and continually using additional opioids on top of their current treatment

Prolonged-release buprenorphine is not recommended under the following circumstances in community settings:

- Contraindications stated in the SPC
- Service users who refuse treatment
- Service users who lack capacity to consent to treatment

6.2 Health and Justice settings

Many of the issues described in community settings (section 6.1) also apply in Health and Justice settings. Before the service user is started on prolonged-release buprenorphine, they must be stabilised on oral OST. This is due to challenges associated with arranging follow up care and potential multiple changes to their treatment.

Prolonged-release buprenorphine is recommended as an option for service users who are stable on their maintenance OST, in the following cohorts:

- Service users who have commitments which significantly affects their access to supervised consumption timings, for example due to:
    - Work commitments
    - Regular release on licence for short periods
    - Education commitments
- Service users currently on other OST who are identified suitable prolonged-release buprenorphine candidates and towards the end of their sentences or on parole as part of a release plan in collaboration with community substance misuse services.

Due to challenges associated with arranging follow up care and potential multiple changes to their treatment, prolonged-release buprenorphine is not recommended in Health and Justice settings for the following service user /groups:

- those who are on initial stabilisation phase
- those who are unstable with their current OST regime
- those on short remand. Prolonged-release buprenorphine can be considered in remand prisoners where there is adequate time for the dosing regimen to be stabilised (e.g. usually a minimum of 8 weeks as per the model for released prisoners in Wales) AND suitable arrangements are in place with community providers to ensure that continuity of care would not be compromised upon release. (10)

There may be challenges unique to different settings (see section 8) around procurement, storage, administration, staffing and training which need to be considered when introducing prolonged-release buprenorphine into local substance misuse pathways. Therefore, it requires a system-wide engagement and adequate release planning to ensure continuity of care for service users.
For considerations in particular clinical scenarios, please refer to section 10 for details.

7. Commencing treatment

Healthcare professionals need to be mindful that whilst pharmacological treatment can be effective; it is only acceptable when service users are empowered to make an informed choice. Service user communities are concerned about the risk of coercive use for extended-release OST. A person-centred approach needs to be considered when deciding the choice and appropriateness of OST whilst balancing the need for professional curiosity when a service user refuses an effective treatment which has no currency or abuse potential and requests the drug form that can be abused or traded. (11)

There needs to be an agreement with the service user and substance misuse service provider that regular psychosocial interventions will continue because OST and psychosocial interventions go hand in hand to support a service user through their recovery journey.

To avoid risk of precipitated withdrawal, treatment should only be started when objective and clear signs of mild to moderate withdrawal are evident. Consideration should be given to the types of opioid used (that is long- or short-acting opioid), time since last opioid use and the degree of opioid dependence. The initial dose of Buvidal can only be administered after at least 4-6 hours of the last short-acting opioid dose (e.g. heroin, morphine) with objective evidence of withdrawal (e.g. Clinical Opiate Withdrawal Scale (COWS) >10). (1,2)

7.1 Buprenorphine naïve service users

The manufacturer recommends giving service users a test dose of 4mg sublingual buprenorphine and observe for an hour. If the service user does not show signs of hypersensitivity or other significant effects to buprenorphine, it is recommended to start the service user on weekly buprenorphine injection. (1,2)

The recommended starting dose by the manufacturer is 16mg weekly, with the option of topping up with 8mg for one or two doses at least one day apart within the first week. The target dose is 24mg or 32mg in the first week. It is recommended to schedule a medication review 3-5 days after the first dose to address any issues which have occurred with the medication and give top ups where

necessary. The recommended dose from the second week onwards will be the total dose administered during the first week. (1,2)
Once service users have been stabilised on weekly Buvidal for four weeks as per manufacturer's recommendations, they can switch to monthly injections. (1,2)

7.2 Switching from other buprenorphine products to Buvidal

Service users on sublingual buprenorphine can be switched to Buvidal directly according to the dose recommendations in the table below: (1,2)

Table 3. Dose conversion of daily oral buprenorphine to subcutaneous Buvidal (from Buvidal SPC)

Dose of daily generic sublingual buprenorphine	**Weekly Buvidal dose**	**Monthly Buvidal dose**
2-6 mg	8 mg	-
8-10 mg	16 mg	64 mg
12-16 mg	24 mg	96 mg
18-24 mg	32 mg	128 mg

Some providers use buprenorphine oral lyophilisate (Espranor) which is not interchangeable with other buprenorphine products (i.e. generic sublingual buprenorphine or Subutex). This is because the bioavailability of buprenorphine is 25-30% higher with Espranor as it is more completely absorbed compared to sublingual tablets. (1,2,12) Due to individual variability of buprenorphine pharmacokinetics, it is recommended to titrate the Buvidal dose according to the service user's clinical response. (12)

It is advisable to ensure closer monitoring during the initial switching period as it is a new formulation being given. (1,2) Service users need to be counselled and monitored for increased withdrawal or craving symptoms or instability issues.

7.3 Switching from methadone to Buvidal

There is no direct conversion from methadone to Buvidal. The recommendation is to reduce the methadone dose to maximum 30mg/day before starting treatment. (1,2) Buvidal must not be administered until at least 24 hours after the last dose of methadone. This is to avoid precipitating withdrawal symptoms. The initiation schedule will be the same as buprenorphine naïve service users.

7.4 Missed or delayed doses

Weekly doses can be administered up to 2 days before or after the weekly dose is due. Monthly doses may be administered up to one week before or after the monthly dose is due. (1,2)

7.5 Discontinuing treatment

Consider discontinuing treatment if the service user failed to maintain benefit from Buvidal in scenarios outlined in section 4.6 Drug Misuse and Dependence: UK Guidelines on Clinical Management. Depending on the clinical scenario, the clinical response may involve switching to an alternative OST to provide a better target response. (5) Some service users may choose to discontinue prolonged-release buprenorphine as part of their abstinence recovery goal. Discontinuing Buvidal with a goal of abstinence is not within the scope of this guidance and off-label. The following section offers guidance to scenarios where Buvidal is required to be switched to another OST.

7.5.1 Switching Buvidal to buprenorphine sublingual or supralingual

Start the alternative OST when the next Buvidal dose is due (e.g. 5-9 days after last weekly Buvidal dose or 3-5 weeks after last monthly Buvidal dose). Refer to Table 3 as a guide for initial dose conversions. Please refer to SMMGP/FDAP Clinical Guidelines for Use of Depot Buprenorphine (Buvidal) in the Treatment of Opioid Dependence for further guidance. Due to individual variability of buprenorphine pharmacokinetics, frequent clinical reviews will be required initially to optimise buprenorphine sublingual or supralingual dose over the subsequent days according to clinical need. (6,12)

7.5.2 Switching Buvidal to methadone

There is limited clinical experience for directly switching service users on Buvidal to methadone. SMMGP/FDAP Clinical Guidelines for Use of Depot Buprenorphine (Buvidal) in the Treatment of Opioid Dependence recommends transitioning the switch via buprenorphine sublingual or supralingual. Once stabilised on buprenorphine sublingual or supralingual for at least 4 weeks, consider initiating methadone at low doses (20-30mg daily) with frequent clinical reviews and titrate accordingly. (4)

8. Practical considerations in different care settings

8.1 Legal status and storage

In England buprenorphine is a Schedule 3 (CD no register) controlled drug. This needs to be stored and supplied in line with the Misuse of Drugs (Safe Custody) Regulations 1973 and NHS England Area Team Health and Justice Prison Medicines Management Standards.

To avoid risk of diversion and misinjecting, Buvidal **must not be in the possession of the service user** (even as a dispensed medicine) and **can only be administered by a registered healthcare professional.** (1,2)

If the substance misuse service provider (SMSP) chooses to have medication issued by community pharmacies, medication could be either delivered directly to the service or SMSP staff collect on the service user's behalf directly from the pharmacy. A signed agreement between the SMSP and the service user for collection, possession and destruction if unused is recommended (see sample agreement in Appendix 5).

8.2 Potential delivery models

It is recognised that different providers would choose different ways to deliver this service, depending on current set up. Please refer to Appendix 2 and Appendix 3 for comparison of suggested different delivery models which may be adapted locally according to service needs.

8.3 Training

There are currently no formal prescribing or administration training requirements for Buvidal. However, organisations may wish to develop local training packages as this is a relatively new product. Additional administration training is recommended for services where registered HCP are not already trained to administer subcutaneous injections. There is no formal national training package available for subcutaneous injections. Organisations may wish to link in with the manufacturer for training support. SMSPs are advised to ensure sufficient staff (including locums) are trained for service resilience. If the administration is delivered by a third party (e.g. community

pharmacy), SMSPs are advised to have evidence of training to ensure competence and that training is up to date.

The needle shield of the safety syringe may contain rubber latex which may cause allergic reactions in latex-sensitive individuals. (1,2) There is also a risk of anaphylaxis with parenteral medications. In line with Resuscitation Council UK guidelines, clinical staff who administer parenteral medications should have initial training and regular updates in dealing with anaphylactic reactions. (13) Adrenaline needs to be available for anaphylaxis emergencies as required by Resuscitation Council UK guidelines and Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 12. (13,14)

8.4 Protocols

Depending on how prolonged-release buprenorphine is delivered, there might be multiple groups of HCP or staff involved in the service user's care which may not necessarily be employed by the same organisation. From current UK pilots, it is recommended to have clear organisation protocols in place to outline defined responsibilities for each team involved in service user's care. The protocols in place should cover how and who to escalate issues with the service user's wellbeing, especially where there is a reduced contact with prolonged-release buprenorphine.

If the administration is delivered by a third party (e.g. community pharmacy), SMSPs are advised to have an oversight of their local protocols before signing up to the scheme. It is also recognised that some service users may miss their scheduled injection for various valid reasons (e.g. work commitments). SMSPs may want to consider having some flexibility around administration dates in those situations, and if applicable would need to be covered in the service level agreement with the third-party provider.

In community settings, it is recommended to have "did not attend" and "unsuitable for administration" procedures in place for situations where service users fail to attend their scheduled appointments or the dose is not administered due to clinical reason (e.g. service user is too intoxicated to provide consent). (15) The procedures should contain the following:

- Communication system (i.e. who to inform- keyworker, clinician)
- Documentation
- Actions to be taken to contact and recall the service user if applicable. It should detail who is responsible for carrying out these actions.
- Key workers should prepare an individualised "Did Not Attend" plan for each person prescribed prolonged-release buprenorphine. This will inform staff unfamiliar with the service user of the actions to be taken when they do not attend appointments.

All organisations are expected to have local protocols in place for safe handling, storage and transport of controlled drugs. It is not a legal requirement to have Buvidal administration witnessed by another suitably trained healthcare professional. However, this is a recognised good practice in accordance with NPSA guidance. (16) Having a second witness is an issue especially in outreach scenarios. Buvidal may be administered without a witness under such circumstances, provided this has been risk assessed and deemed appropriate by the SMSP. (16,17)

8.5 Record keeping

Good record keeping as outlined in NICE NG46 is necessary to prevent medication incidents. (17)

As with other prolonged-release injections, it is recommended to document the following in the service user's records: (15,17)

- Name of medicine and dose given
- Date of administration
- Site of administration (to avoid reinjecting the same site)
- Next due date
- Any noted side effects
- Details if dose refused or not given

9. Transfer of care

9.1 General principles

It is recognised that the service user's care may be transferred to another provider (acute/ community/ mental health/ health and justice) and vice versa. There should be clear documentation and communication between healthcare professionals at both settings to minimise disruption to the service user's treatment and ensure continuity of care.

As a minimum, the following needs to be communicated to the receiving provider upon transfer:

- date and dose of last dose administered
- date and dose of next dose due
- current dosing regime (and equivalent dose of sublingual or supralingual buprenorphine should Buvidal need to be converted back)
- preferred site of administration, including last site of administration
- dose titration regime if the service user is not on a stable regimen
- if applicable, where service user normally receives treatment (e.g. directly from SMSP, community pharmacy)
- monitoring required
- contact details of the transferring team, if further information is required

As prolonged-release buprenorphine is still relatively new and may be missed in medicines reconciliations especially in secondary care, good communication may be enhanced by transferring a copy of the prolonged-release prescription and recording sheet as the service user moves. It is imperative to inform the service user's GP, so that this can be updated in the service user's summary care records. The GP should be asked to include the service that provides this treatment on their prescription record. This would also be useful in the event the service user cannot communicate (e.g. unconscious).

9.2 Planned transfers

A locally agreed care pathway between SMSPs, such as between a prison provider and a community provider **must be in place before treatment can commence**. It would be preferred for the service user to be stabilised on monthly injections before discharge.

Where the transfer is planned, enough notice needs to be given to the receiving provider to ensure they can seamlessly continue treatment.

Where the receiving provider does not have appropriate facilities to administer prolonged-release buprenorphine (e.g. due to local commissioning arrangements), plans **must be made before transfer** between the initiating and receiving provider about when and how to switch to an alternate OST in accordance with local formularies. This will prevent issues on OST continuity or omitted and delayed doses on transfer.

9.3 Unplanned transfers

If the service user is due for a dose on the day of transfer or court hearing, it would be preferred for the service user to have a dose before leaving the prison facility. However, sometimes this may not be possible. If the dose is unable to be administered on time, weekly doses can be administered up to 2 days before or after the weekly dose is due. Monthly doses may be administered up to one week before or after the monthly dose is due. (1,2)

Where the transfer is unplanned, written documentation should be provided, followed by a verbal handover on the next working day. If the receiving provider is not commissioned to provide Buvidal, the responsibility to switch to OST transfers to the receiving provider. As Buvidal is relatively new, receiving providers who are unfamiliar with the service delivery models of Buvidal would require clear communication about differences in administration frequency, doses and service delivery models. (18)

Transition between Buvidal and sublingual or supralingual buprenorphine is more straightforward and service users can be initiated at an equivalent dose of sublingual or supralingual buprenorphine when the next Buvidal dose is due. There is limited clinical experience for switching between Buvidal and oral methadone. Please refer to section 7.5 for treatment switching guidance. Receiving providers are encouraged to work with the initiating provider to minimise disruption to the service user's treatment.

9.4 Hospital transfers

As mentioned in Section 9.1, prolonged-release buprenorphine could be missed from medicines reconciliations and discharge summaries from secondary care because it is not given daily and might be missed off drug administration charts. This may be clinically relevant especially in clinical scenarios listed in Section 10. Hospital staff are advised to follow section 7.5 of Drug Misuse and Dependence: UK Guidelines on Clinical Management recommendations, which includes: (6)

- liaising with SMSPs for advice and support if appropriate
- appropriate communication between key professionals in hospital and SMSPs to ensure safe, effective, and seamless care. This includes making appropriate plans for continuing OST prescribing in SMSPs after discharge.

This is to ensure service users are being managed appropriately for both medical and dependence issues. The information which is required on transfer has been discussed in Section 9.1.

Hospital staff may not be familiar with Buvidal because this is a relatively new product at the time of writing. SMSPs will need to support hospital staff when they are contacted or as part of routine collaboration, about the difference in doses, regimes, and formulations available for weekly and monthly of Buvidal. This is to ensure the correct products are selected and administered correctly, if appropriate whilst being treated medically in hospital.

10. Clinical scenarios

Most of the information below has been extracted from SMMGP/FDAP Clinical Guidelines for Use of Depot Buprenorphine (Buvidal) in the Treatment of Opioid Dependence. Please refer to Section 7 of that guidance for further information. (4)

10.1 Overdose

Normally the use of prolonged-release buprenorphine on its own is rarely associated with overdose. In the context of polydrug use (e.g. alcohol, central nervous depressants, benzodiazepines), overdose can occur. General supportive measures (e.g. respiratory support, cardiac and respiratory monitoring) are recommended. In clinical practice, regular doses of naloxone have been used to manage polydrug overdoses implicated by buprenorphine. (1,2,4) Please refer to SPC and Toxbase for case specific advice on more complex cases.

The specific potential risks of the prolonged-release buprenorphine injections are the prolonged plasma levels of buprenorphine, rather than higher plasma levels compared to sublingual dosing, hence there may be no greater risk of overdose occurring from prolonged-release buprenorphine formulations. (4) Due to its extended-release profile, SMMGP/FDAP Clinical Guidelines for Use of Depot Buprenorphine (Buvidal) in the Treatment of Opioid Dependence recommended service users on Buvidal to be clinically monitored for extended periods of time, until they have recovered. They may require prolonged monitoring and a naloxone infusion in a hospital setting. (4)

10.2 Polydrug use and regular intoxication

If the service user presents acutely intoxicated when the prolonged-release buprenorphine injection is due, the service user needs to be assessed to identify any safety concerns about dosing. Clinicians would also need to consider the substance abused (e.g. alcohol, novel psychoactive substances) as part of the clinical assessment. It will be a clinical decision whether to administer/ omit the dose or switch to an alternate OST on a case-by-case basis. If there are concerns that the service user is too intoxicated to provide consent, the dose administration may be deferred. Acute alcoholism and delirium tremens are absolute contraindications. (1,2)

Service users who have patterns of regular and harmful substance misuse often may benefit from regular clinical monitoring and review. The monthly prolonged-release buprenorphine injection reduces the frequency of contact between service users on OST and healthcare professionals compared to service users on oral OST. This potentially makes it harder to identify potential health and social issues earlier. In such cases, consider using medications with more frequent dosing intervals. Depending on the type of substance misused (e.g. alcohol, cannabis, novel psychoactive substances), service users may require specific psychosocial interventions to reduce or stop use of those substances. (4)

10.3 Pain management

Buvidal is not licensed for pain, but it is recognised that its use may impact general pain management. Buprenorphine is a partial mu agonist, therefore adequate analgesia may be difficult to achieve with full opioid agonists (e.g. morphine). (4)

Pain and substance misuse: improving the patient experience recognises that both acute and chronic pain are complex sensory and emotional experiences which can be influenced by biological, psychological, social and cultural factors. In chronic pain, there will be several predictable psychosocial consequences which will require support and management. Due to the complexities involved, it is recommended to have a joint multi-disciplinary approach between specialist pain

management services, SMSPs and/or primary care to support effective management of service users on OST and safe prescription of controlled drugs for pain. This would involve a comprehensive assessment of pain and substance misuse (including alcohol) of the service user. (19)

In a small group of service users, there will a genuine need to use opioids. (20) Clinicians need to recognise that service users may resort to illicit drug use for undertreated pain. However, clinicians would need to be aware of the risks of opioids prescribed for pain being diverted. (19)

Opioids Aware has highlighted the following key principles on safe opioids prescribing: (21)

1. Opioids are very good analgesics for acute pain and for pain at the end of life, but there is little evidence that they are helpful for long term pain.
2. A small proportion of people may obtain good pain relief with opioids in the long-term if the dose can be kept low and especially if their use is intermittent. However, it is difficult to identify these people at the point of opioid initiation.
3. The risk of harm increases substantially at doses above an oral morphine equivalent of 120mg/day, but there is no increased benefit: tapering or stopping high dose opioids needs careful planning and collaboration.
4. If a service user has pain that remains severe despite opioid treatment it means they are not working and should be stopped, even if no other treatment is available.

10.3.1 Acute pain management

Buprenorphine is expected to have little impact in mild, acute pain where a combination of analgesia medications (e.g. non-steroidal anti-inflammatory drugs (NSAIDs), paracetamol), physical therapies and local anaesthetic procedures can be used. (4,6,19) Analgesia medications should be subsequently stepped down and stopped to prevent long-term use. (20)

In moderate to severe acute pain (e.g. trauma) which is more applicable in hospital settings, Drug Misuse and Dependence: UK Guidelines on Clinical Management recognises that opioid treatment is the mainstay of treatment and this applies equally to opioid dependent service users. (6) There will be a genuine need to use opioids in a small group of service users. However, due to the potential complexities involved, specialist pain team advice should be sought. If opioid analgesia is indicated, it should be prescribed at the lowest effective dose for the shortest possible duration in accordance to local formularies and guidance, for example Safer Prescribing in Prisons- guidance for clinicians. (20)

If opioids analgesia is indicated, Drug Misuse and Dependence: UK Guidelines on Clinical Management recommends the following general approaches for service users on OST: (6)

- Using higher doses of opioids (e.g. morphine) initially, which will require tapering down and careful monitoring of side effects.
- Prescribing naloxone and have this readily available if opioids are used.
- Using non-opioid analgesic approaches (e.g. regional anaesthesia) where possible.

In addition to the advice above, SMMGP/FDAP Clinical Guidelines for Use of Depot Buprenorphine (Buvidal) in the Treatment of Opioid Dependence recommends consider using mu opioid receptor super agonists such as fentanyl that themselves have higher mu intrinsic activity than buprenorphine. (4) If naloxone is used, the clearance rates for both prolonged-release buprenorphine (which is longer) and naloxone (which is shorter) will need to be considered.

Note some of the above would only apply depending on where the service user is treated (e.g. in hospitals where specialist pain team input is available). A similar approach can be used in service users treated with prolonged-release buprenorphine in emergency situations. However, buprenorphine plasma levels cannot be reversed in service users treated with prolonged-release buprenorphine.

10.3.2 Chronic pain management

Chronic pain is common in service users on OST and can be managed or "masked" by high doses of methadone or buprenorphine. There is currently no evidence for chronic pain management in service users on high dose sublingual, supralingual or prolonged-release buprenorphine. Buprenorphine has been historically used to manage pain (e.g. weekly topical patches), therefore it is possible that prolonged-release buprenorphine may also be beneficial as part of the chronic pain treatment plan. (4) However, the use of Buvidal for pain management is off-license and not covered by this guidance.

The general principles of chronic pain management in OST would apply as outlined in Drug Misuse and Dependence: UK Guidelines on Clinical Management (see also Section 10.3). This includes appropriate use of opioid and non-opioid medications (e.g. paracetamol, NSAIDs), psychosocial interventions (e.g. cognitive behavioural therapy), physical rehabilitation and exercise. (6)

In palliative care, normally the service user's OST would be treated as a separate entity to their analgesic regime. It is recommended to seek advice from specialist palliative care teams in the first instance. Service users are expected to continue with their usual OST during their inpatient stay, however on discharge separate follow ups for substance misuse and palliative symptoms management needs to be arranged, except in end-of-life scenarios. Analgesic medications should be titrated accordingly, and clinicians should recognise the difference between symptoms of withdrawal and poor analgesic response. Please refer to Pain and substance misuse: improving the patient experience for further guidance. (19)

11. Resource implications

The drug acquisition costs of buprenorphine tablets and methadone oral solution are lower than the weekly or monthly cost of Buvidal but other costs may be reduced by using prolonged-release buprenorphine. The price comparison tool, in the separate attachment, serves as a guide for commissioners to estimate costs involved for the delivery models chosen. The tool references February 2021 Drug Tariff prices which can be amended with local pricing arrangements to reflect true local costs.

Table 4 outlines the potential benefits and disadvantages of different models of delivery, taking into account the extra resources which may not be easily quantified in the price comparison tool.

11.1 Other potential indirect cost benefits

Currently there is anecdotal information to suggest different forms of OST may have economic benefits in Health and Justice, healthcare, and social pathways. These may include: (22,23)

- Reduced risk of diversion both in Health and Justice and community settings
- Reduced number of hospital admissions due to substance misuse
- Reduced number of drug-related crime to fund substance misuse habits
- Contribution to the economy by supporting the service user into gaining stability and a 'drug free' life via undisrupted employment or education

- Reduced number of overdoses related to substance misuse

The actual impact across the health or criminal justice economy will become clearer as further research of these factors is published. These costs have not been quantified as part of this guidance and are out of its scope.

Table 4. Advantages and disadvantages of different delivery models for administering Buvidal

Model	Advantages	Disadvantages
Health and Justice Buvidal administration by suitably trained registered healthcare professional	- Reduced supervision time for daily oral OST supervision, which will release personnel time (healthcare and prison security) - Reduce missed doses for prisoners who are unable to pick up their daily OST in the morning due to court hearings/ work - Reduce risk of diversion	- Depending on the prison's current operational set up and injection appointment availabilities, Buvidal may not be an operational cost saving. Prisoners may require escorting individually if not receiving treatment at the same time. - Overall cost of Buvidal is still more expensive - May require prisoners to be escorted to a different part of the prison which is not next to current place of administration - Additional considerations for secure medicines storage, as normally prisoners are not allowed into rooms where medication is stored - Potential lack of continuity of care if prisoner moves and the receiving provider does not offer Buvidal in their service
Community – Model 1 Administration on-site at SMSP premises by SMSP with Home Office licence	- Reduced administrative burden associated with daily OST supervision - Allows OST administration where service users are banned from community pharmacies due to antisocial behaviour - Ability to detect and address disengagement with service user directly with consistent patient contact - Ability to store and administer drugs on site. Access to locally agreed drug prices	- Lack of accessibility to treatment out of clinic hours - Expensive if require set up of facilities. This includes: - Home Office licence or registered pharmacy status - Modification to buildings to have CQC compliant clinic rooms and installation of controlled drugs cabinet - May need to increase clinic capacity to administer drug - Need to attend clinic for injection instead of self-administration compared to oral OST - Increase cost if service user does not attend appointments regularly and requires frequent dose titrations
Community- Model 2 Administration on-site at SMSP premises by SMSP without Home Office licence/ registered pharmacy status	- As per Model 1 but without the ability to access locally agreed drug prices - Clinics may be able to store drugs on site if they have controlled drugs cabinets.	- As per model 1 minus the cost of Home Office licensing fee. - Will need an agreement to either have medication delivered directly on site or collected from pharmacy by clinic staff.
Community- Model 3 Administration in community pharmacies	- Better accessibility out of hours - Reduce time for daily supervision, which will release community pharmacists' time	- Need to attend pharmacy for injection instead of self-administration - Not all pharmacies will sign up for this scheme. May limit service user choice - Relies on good communication between community pharmacy and the substance misuse clinic to identify issues promptly. - Reduced contact- reduced potential to identify issues with service users' health promptly - Risk of coercion by service users to give medication not at the scheduled times. - Risk of disengagement from psychosocial interventions with substance misuse clinic. - Lack of flexibility to give medications as scheduled for service users who genuinely cannot attend their planned administration date. This could be resolved by having a local SLA in place.
Community – Model 4 Administration at off-site venue at non-SMSP premises by SMSP as part of outreach service with home office licence	- As per Model 1, with potentially better access to service users via outreach service	- As models 1 & 2. Difficulty in obtaining permission to modify building which does not belong to SMSP. Additional risk assessments and protocols for safe transportation of controlled drugs - Additional risks assessments to ensure appropriateness of administration venues (i.e. satellite clinics, service users' homes). Potential safety risk to clinical staff administering if working alone - Additional cost for staffing outreach service

12. Recommendations

Prolonged-release buprenorphine, Buvidal presents as a suitable OST option for specific cohorts of opioid dependent service users. This is an alternative OST along with other forms of buprenorphine and methadone based OSTs. Careful considerations around patient selection are important as Buvidal may not be suitable for all opioid dependent service users. It is also important to consider the service users' wishes in arriving at the choice of most suitable form of OST as part of their recovery plan.

Buvidal is a more expensive medication in comparison to other forms of OST (22), with possible costs associated with administration. However, prolonged-release buprenorphine may address an unmet clinical need in specific cohorts of service users which may support them into gaining stability and a 'drug free' life, for example via undisrupted employment or education.

SMSPs and commissioners are advised to use the criteria outlined in this document to identify specific cohorts of service users who may benefit most from this treatment, whilst being mindful of the considerations associated with implementing Buvidal safely in local substance misuse pathways.

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Appendices

Appendix 1: Patient information leaflets

The manufacturer has produced a website and patient information leaflets, available at:

https://www.opioiddependenceandme.com/

https://www.buvidal.co.uk/resources/

https://www.medicines.org.uk/emc/product/11418/pil

There are several patient information leaflets available which has been developed by the other organisations:

https://www.kaleidoscopeproject.org.uk/wp-content/uploads/sites/25/2020/05/FINAL-APPROVED-COP.-Buvidal-21Qs.pdf

https://www.choiceandmedication.org/ (subscription required)

Please also refer to Appendix 5 "additional service user information" **Appendix 5: Pre-initiation consent form for Buvidal**for quick fact sheet on Buvidal developed by Turning Point.

Note some of the local practices may differ with different substance misuse service providers. Substance misuse service providers who choose to use these leaflets may want to adapt locally if necessary. RMOC does not endorse or advocate these leaflets should be used in preference to the manufacturer's guidance.

Appendix 2: Comparison of oral OST versus prolonged-release buprenorphine delivery in Health and Justice

Oral OST (e.g. methadone)		**Prolonged-release buprenorphine (Buvidal)**
Short, daily	Dose administration times 	Longer, less frequent (but may not occur at the same time)
Based on medicines queues length	Appointment times	Based on time of arrival at the waiting room for appointment and time of escorting back to the wing
Prisoners can be grouped together to have OST at the same time and being administered along with other non-in possession medicines	Clinic capacity 	Needs increasing to accommodate longer individual administration May not happen at the same time
Given **orally** by 1 suitably trained HCP (witnessed by another HCP*)	Administration by medical personnel 	Given as a **subcutaneous** injection by 1 suitably trained HCP (witnessed by another HCP*)
Prisoners can be grouped together to have OST at the same time and being administered along with other non-in possession medicines	Prison officer 	Depending on the prison security and regime and health delivery arrangements, may need to increase staffing resource to ensure prisoners can access appointments if this cannot be accommodated within existing healthcare clinics and healthcare escorts
Oral administration, less complex training required. Most organisations are familiar with oral OST	Training 	Unless already trained to administer (e.g. nurses), would require additional local administration training including anaphylaxis training. Local training required initially for prescribing
- Normally administered at pharmacy dispensing hatch or healthcare wing - SMSPs would either have access to pharmacies on-site or may have local agreements in place to purchase medicines from external pharmacies and stored on-site	Estates 	- Requires separate administration area (e.g. treatment room) which may not be at the same place as oral OST - CD cupboard and register for storage in treatment room if required locally - Adrenaline needs to be available for anaphylaxis emergencies
Most organisations would have home office licence or registered pharmacy status in place for storage and/or ordering CDs, which is renewed annually	Licensing 	Same as oral OST
- **Prisoners are expected to have OST daily so no extra local administration mechanisms are required to be in place.** - More diversion risk	**Other**	- May require extra local mechanisms in place (e.g. booking future appointments) to ensure future dose administrations are scheduled - Less diversion risk

*May be part of SMSP local policy but not a legal requirement

Appendix 3: Comparison of different service delivery models for prolonged-release buprenorphine in community

Description	Model 1- On-site at SMSP premises by SMSP with Home Office licence	Model 2- On-site at SMSP premises by SMSP without Home Office licence	Model 3- Off-site by community pharmacy	Model 4- Off-site venue at non-SMSP premises by SMSP as part of outreach service with Home Office licence
Location of administration	On-site at SMSP premises (e.g. clinics, inpatient day cases)	On-site at SMSP premises (including satellite clinics)	Community pharmacy	Off-site at suitable venue (e.g. satellite clinics, patient homes) by SMSP as part of outreach service
Route of medication supply	Stock	Community pharmacy	Community pharmacy	Stock
Home office licence cost to SMSP (renewed annually)	✓	✗ (cost already carried by community pharmacy)	✗ (cost already carried by community pharmacy)	✓
SMSP access to locally agreed drug prices	✓	✗	✗	✓
Clinic appointment times	Longer but less frequent	Longer but less frequent	Not applicable, less frequent unless additional monitoring required	Longer but less frequent
Clinic capacity	Needs increasing to accommodate longer individual administration	Needs increasing to accommodate longer individual administration	Not affected, expected to be less frequent unless additional monitoring required	Needs increasing to accommodate longer individual administration
Staffing	Needs increasing to cope with extra clinic capacity. All staff administering would require	Needs increasing to cope with extra clinic capacity. All staff administering would require appropriate	**SMSP**: not affected **Pharmacy:** needs to have enough trained staff to ensure service continuity. Administration is normally	Needs increasing to cope with extra clinic capacity. All staff administering would require appropriate indemnity insurance

	appropriate indemnity insurance	indemnity insurance	expected to be undertaken by pharmacists, who will require appropriate indemnity insurance to administer injectable medicines	
Training for administration 	Unless already trained to administer (e.g. nurses), would require additional local administration training.	Unless already trained to administer (e.g. nurses), would require additional local administration training.	- Would require additional local training. Currently there is no national training scheme available for subcutaneous injection. - Proof of training required by SMSP to ensure up to date.	- Unless already trained to administer (e.g. nurses), would require additional local administration training. - Training and risk assessment for lone working if applicable
Estates and facilities 	- Modification to existing buildings to create CQC compliant clinical rooms - Addition of CD cupboards, CD register for storage in lockable rooms	- Modification to existing buildings to create CQC compliant clinical rooms - Addition of CD cupboards, CD register for storage in lockable rooms if required locally in case drug not administered	**SMSP**: not affected **Pharmacy**: not affected, most pharmacies would have separate consulting rooms which can be used for administration	Permission to modify existing non-SMSP buildings to: - create CQC compliant clinical rooms - add CD cupboards and CD register for storage in lockable rooms SMSP may consider storing drugs at nearest SMSP-owned site which has suitable storage facilities and bringing to off-site venue for administration in suitable locked receptacle
Pharmacy supervision cost 	Not applicable	Not applicable	Locally agreed administration tariff payable to community pharmacies	Not applicable
Protocols/ risk assessments/ audits 	Refer to section 8.4 - Additional protocols for safe handling and transportation of CDs (e.g. locked box, register)	Refer to section 8.4 Additional protocols for SMSP for CD destruction as unable to reuse drug as it is labelled for a specific service user and cannot be reused for a different service user	Refer to section 8.4 - Additional local pharmacy protocols for administration - Regular audits by SMSP to ensure compliance to local protocols	Refer to section 8.4 - Additional protocols for safe handling and transportation of CDs (e.g. locked box, register) - Risk assessments of suitable off-site administration venues which may not necessarily meet clinical room standards

Appendix 4: Pre-initiation checklist for Buvidal

To be adapted locally if required

1.	Service user has been explained:	
	- why they are started on buprenorphine	☐
	- the different drug options available, with the pros and cons	☐
	- how long it takes to act	☐
	- how and where it is given	☐
	- the importance of psychosocial therapy and drug treatment is effective if it is used alongside	☐
	- side effects	☐
	- risks of harm associated with excessive alcohol intake, taking medications (prescription and non-prescription) not under clinical supervision, taking recreational substances whilst on Buvidal. When used with certain substances (e.g. novel psychoactive substances), the potential effects are unknown due to lack of data.	☐
	- what to do if they missed a dose or unable to attend appointment	☐
2.	Check for drug interactions and allergies. Inform patient to check any new drugs with the prescriber, especially painkillers.	☐
3.	Check baseline liver function test and hepatitis status. Explain the importance of having liver function tests done regularly.	☐
4.	Service user has been given the drug company's Patient Information Leaflet and Drug Alert Card. They are encouraged to carry the Drug Alert Card with them at all times.	☐
5.	If prescribed in community, service users understand that they are not allowed to be in possession of the medication.	☐
6.	If applicable, sign consent form to allow clinic staff to collect medication on behalf of patient	☐
7.	Service user can exit treatment if the medication does not suit them	☐
8.	Explain to service user that they need to be in opioid withdrawal before initiation. If they are not, this means they may need to come back to the service on a different day	☐
9.	For buprenorphine naïve service users- explain that they will need to have a test dose of oral buprenorphine and observed for an hour before having the medication.	☐
10.	Not all services may offer Buvidal. If the service user gets transferred into a service which does not offer Buvidal, they may be switched to an alternative treatment.	☐
11.	Explain wash-out period to service user	☐
12.	Offer chaperone to service user	☐
13.	Ask service user if they have further questions. Provide a point of contact for further queries	☐

Appendix 5: Pre-initiation consent form for Buvidal

(Adapted with permission from Turning Point)

Buvidal is a prolonged-release injection containing buprenorphine. It is administered either weekly or monthly for opioid dependency for people aged 16 and over.

Your prescriber has recommended Buvidal as an option for your treatment.

I, the undersigned, confirm that (please tick box as appropriate):

1.	I have read and understood the information about Buvidal, as provided in the Patient Safety Information booklet and Patient Alert Card.	☐
2.	I have been given the opportunity to ask questions about Buvidal	☐
3.	I understand that I will need to attend at this clinic every week and/or month and I will be given an appointment card with the details of my next appointment	☐
4.	I understand that there is a risk of harm with drinking alcohol excessively, taking medicines without clinical supervision, or using street drugs during Buvidal treatment. These effects could be unknown, potentially serious, and life-threatening.	☐
5.	(For females) I am not pregnant or breast feeding	☐
	Questions 6 and 7 apply to service users in the community only	
6.	I understand that although my Buvidal is prescribed for me, it will be delivered by the community pharmacy to the clinic or a member of staff will collect on my behalf and I will not be "in-possession" of the medication	☐
7.	I understand that the staff will ask for both confirmation and evidence of my exemption from paying the NHS prescription charge **or** will ask me to sign the exemption declaration in the service **or** will request that I attend the pharmacy to pay the prescription charge in advance of *[insert SMSP name]* collecting the medication.	☐
8.	I understand that *[insert SMSP name]* can only guarantee prescribing for a period of *[insert duration]* and whilst I am residing in this area. If we cannot an alternative buprenorphine (or other opioid substitution treatment) will be offered	☐
9.	I understand I need to be in opioid withdrawals before starting my Buvidal. This may necessitate my returning to the service on a different day if I am not.	☐
10.	**For buprenorphine naïve clients only**I understand I will be given an oral dose of buprenorphine (4mg) first and will need to stay in the service for 1 hour before the administration of the Buvidal	☐
11.	**Wash-out period:** If Buvidal is stopped; its long-acting properties and any withdrawal symptoms will be considered by your prescriber. If you are switched to oral buprenorphine, this will be done one week after the last weekly dose or one month after the last monthly dose	☐
12.	I have been offered a chaperone and have accepted this. The name of my chaperone is …… **OR** I have been offered a chaperone but declined	☐

Service User:

_____	_____	_____
Service User	Signature	Date

Clinician:

_____	_____	_____
Clinician	Signature	Date

Additional service user information

(Adapted with permission from Turning Point)

- Buvidal is the trade name for a buprenorphine long-acting injection
- It is used to help people get off opioids such as heroin and morphine
- The usual dose is 8-32mg every week or 64-128mg every month
- Buvidal will be administered by a trained healthcare professional only
- The peak effects from the weekly injection are seen after around 24 hours while for the monthly injection this is between 6 and 10 hours. The weekly injection can be given up to 2 days either side of the due date, and the monthly up to 7 days either side of the due date. However, it is very important to keep your appointment date as appointment slots are limited and if you miss your appointment, we cannot guarantee that we will be able to find a suitable alternative appointment for you. If you know you will have difficulty attending your appointment, please let your recovery worker know as soon as possible.
- Buvidal and alcohol and/or other drugs (poly-substance use) can increase your risk of an overdose.
- You may require a regular blood test called a Liver Function Test or LFT. Your prescriber will inform you who would carry out these tests and support you if needed. This is because in rare circumstances buprenorphine can affect how your liver works especially if you currently have a liver problem.
- Like any other opioids, Buvidal can make you drowsy especially if mixed with alcohol. You should not drive if you feel drowsy with any drugs.
- If you appear to be under the influence of any substances including drugs or alcohol and cannot agree to have an injection, we will not be able to give your injection. We will need to delay your injection until it is safe to do so.
- Very common side-effects for Buvidal (>1 in 10) include insomnia, headache, nausea and sweating.
- Common side effects for Buvidal (between 1 in 10 and 1 in 100) include decreased appetite, dizziness, fainting, constipation, vomiting and muscle aches.
- You may also have a local reaction at the injection site which includes pain, itching, redness and swelling. In the early trials the following injection site-related side-effects were observed:
    - Injection site pain (around 9 in 100 people)
    - Injection site itching (around 6 in 100 people)
    - Injection site redness (around 5 in 100 people)

  All these injection site side-effects were all mild or moderate in severity and mostly short-lived
- If you are worried about a suspected side effect, you should seek medical advice from your clinician. If you think Buvidal has caused a serious unwanted side effect, please report this via the Yellow Card scheme. Further details on this are available at https://yellowcard.mhra.gov.uk/

- Patient Information Leaflets are available at:
    - Buvidal PiL available at https://www.medicines.org.uk/emc/files/pil.9705.pdf
    - Buprenorphine PiL (including information for clients prescribed Buvidal®) available at https://www.choiceandmedication.org/ (subscription only service)

Appendix 6: Post-initiation checklist

To be adapted locally if required

1.	Check service user's well being	
	- how are they feeling in general	☐
	- how do they think they are coping with the medication	☐
	- side effects which are of concern	☐
	- whether service user is still attending psychosocial sessions offered by the substance misuse clinic. Emphasise that medication only plays a part and they will need to engage with the service to help them recover better.	☐
	- compliance with medication	☐
2.	Check for drug interactions and allergies. Check any new drugs initiated	☐
3.	Check liver function test if due. Explain the importance of having liver function tests done regularly.	☐
4.	Ask service user if they have further questions. Provide a point of contact if they have concerns later	☐
5.	Confirm date of appointment for next injection booked with service user. In the event if they are unable to attend the scheduled administration appointment, service user must inform the substance misuse clinic as soon as possible to arrange an alternative appointment date to avoid missed doses.	☐
6.	Confirm drug notification about Buvidal treatment sent to GP	☐