Service Level Agreement

Buvidal (prolonged-release buprenorphine solution for injection) – community pharmacy administration

This agreement is in place between [drug treatment service] and [community pharmacy].

This agreement is effective from [insert date]

Review date [insert date]

Expiry date [insert date]

This sample document has been provided in word format to enable services to edit and

adapt based on local requirements and policies.

This sample document has been developed in consultation with an

established provider.

UK-BUV-2400269, June 2024. Please note, this date and code only relates to the master template and must be removed before being adapted.

|  |  |
| --- | --- |
| 1 | Service description and background |
|  | The provision of long-acting injectable buprenorphine (LAIB) services through community pharmacy aims to support high quality Pharmaceutical Care and choice to patients being treated for opioid dependence within a framework of medical, social and psychological treatment. Long-acting injectable buprenorphine, administration is restricted to healthcare professionals only. This is because prescribing, dispensing, and patient follow-up visits with clinical monitoring is tailored to the patient's needs. Consequently, take-home use or self-administration of this medicine is not permitted within the license.  LAIB is available in weekly and monthly depot injections with flexible dosing that can be increased or decreased as needed.  This Service Level Agreement (SLA) acts as a contract between [drug treatment service] and the named community pharmacy and commits the contractor to provide the services outlined below in the listed supporting documents [please provide list of documents and where to find them]. Services must be provided within the legal and ethical framework of pharmacy as a whole.  This SLA aims to define the role of pharmacy in this collaboration. Effective communication between the partners involved in each patient’s care plays an important part in the effective delivery of this service.  This service will run from [enter dates for initial contract] |
| 2 | Aim of service |
|  | The aim of this service is to offer administration of long-acting injectable buprenorphine at community pharmacy level to:   * Enable community pharmacies to deliver a broader range of opioid substitution therapies * Reduce the pressure on and potentially increase the capacity of, the drug treatment service * Provide care closer to patients' communities and reduce travel time / cost of attending central locations * Administer to [cohort of patients initiated and stabilized by the drug treatment service] |
| 3 | Agreement & sign-up process |
|  | Prior to agreeing to this service and signing of this SLA, pharmacy should ensure the following:   * Risk assessment has been carried out * Relevant SOPs are in place [please list SOPs] * Suitable consultation room is available at community pharmacy to administer long-acting injectable buprenorphine * Relevant training has been delivered/planned [please list training to be undertaken] * Sufficient staffing is in place to support this service and contingency plan in place * Ensure capacity of relevant HCP and support staff |
| 4 | SERVICE SPECIFICATION |
| a | Responsibilities of Superintendent Pharmacist and Pharmacists providing the Service |
|  | Take full responsibility for ensuring compliance with all aspects of the Service Level Agreement (SLA). |
|  | The Community Pharmacy must always ensure there are staff on duty who are aware of the SLA and service to be in a position to discuss and either administer LAIB in accordance with the SLA or schedule administration or support within an agreed timeline. |
|  | The Pharmacy Contractor must ensure that pharmacists providing the service have undertaken training that demonstrates competence in the safe administration of medicines via injectable routes. This could, for example, be provided by compliance with the National Minimum Standards in relation to vaccination training. Additional training in the administration should be provided for the administration of LAIB. |
|  | All training records should be kept up to date and training should be repeated as per the published standards. |
|  | The community pharmacy must ensure that staff are appropriately trained and made aware of the risks associated with the handling and disposal of clinical waste and that correct procedures are used to minimise those risks. A needle stick injury procedure must be in place. |
|  | The community pharmacy must ensure that staff involved in the provision of this service are advised that they should consider being vaccinated against Hepatitis B and be advised of the risks should they decide not to be vaccinated. |
|  | To maintain continuity of service, ensure the Standard Operating Procedure (SOP) in place governing the provision of Buvidal fully covers the main principles of the provision specific to the service standards operating within the pharmacy and that all involved in providing the service are fully conversant with the content of the SOP. |
|  | Maintain stock of agreed list of drugs and nominate a technician/dispenser with responsibility to ensure that sufficient quantities of all stock list medicines and ancillaries are available at all times. Expiry date check must be carried prior to every injection. |
|  | Inform the drug treatment service as soon as any impending changes to personnel involved in the Service are anticipated including sickness of key staff [insert timeframe]. |
|  | In order to provide the service, pharmacies must have a consultation room. The injections should be provided in a room where a patients’ confidentiality is able to be respected.   * The consultation room must meet the General Pharmaceutical Council (GPhC) Standards for Registered Premises. https://www.england.nhs.uk/wp- content/uploads/2018/02/approved-particulars-premises.pdf |
|  | The community pharmacy must ensure the service is accessible, appropriate and sensitive to the needs of all service users. No eligible patient shall be excluded or experience particular difficulty in accessing and effectively using this service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age. |
|  | Ensure patients are treated with dignity and respect and care is delivered in a non-stigmatising, non-judgmental manner. |
|  | Ensure that all pharmacy staff deployed when the pharmacy is open are fully conversant with the principles of the Service and their designated roles and specific responsibilities in providing the service |
|  | Ensure valid patient specific directive is in place and signed by the prescriber |
|  | Ensure that the support and reference materials provided for information, remain current, are retained in the pharmacy and are readily available to all pharmacy staff, including locum pharmacists and dispensing staff. |
|  | Ensure that appropriate advice as per the SmPC is always provided to patients. |
|  | Keep up to date with any changes to the SmPC |
|  | Provide an alert card to the patient as needed indicating date and time of their next appointment. Advise the patient to present to any medical professional from whom they seek help. |
|  | **IF YOU SUSPECT AN ADVERSE REACTION HAS OCCURRED, PLEASE DO NOT GIVE ADDITIONAL DOSES AND CONTACT THE SPECIALIST AT THE DTS**  Any adverse reaction to Buvidal®, or serious reaction will be reported to the DTS and the Medicines and Healthcare Products Regulatory Agency (MHRA) via the “Yellow Card” scheme.  **Adverse events should be reported. Reporting forms and information can be found at** [**www.mhra.gov.uk/yellowcard**](http://www.mhra.gov.uk/yellowcard) **(or search for MHRA Yellow Card in the Google Play or Apple App Store) for the UK and** [**http://www.hpra.ie/homepage/about-us/report-an-issue**](http://www.hpra.ie/homepage/about-us/report-an-issue) **for Ireland. Adverse events can also be reported to Camurus AB via email:** [**safety@camurus.com**](mailto:safety@camurus.com) |
|  | Notify the drug treatment service of missed appointments and rearranged appointments according to SOP |
|  | Follow instructions outlined in the patient specific directive according to dosing windows for LAIB |
|  | Provide drug treatment service with all relevant documentation following administration of LAIB according to SOP |
| c | Responsibilities of drug treatment service |
|  | Carry out initial training [with support from Camurus] for all pharmacists and arrange for pharmacists to shadow a LAIB appointment at the drug treatment service |
|  | Provide support material [or signpost to Camurus, camurus.uk@camurus.com] for each site and update this on a regular basis |
|  | Provide pharmacist with all relevant patient information including medical history, current medication and ways to identify correct patient [to be agreed between local pharmacy and DTS] |
|  | Provide psychosocial treatment and support patient with additional needs |
|  | Ensure patient consent has been obtained to receive treatment at the community pharmacy |
|  | Provide advice and practical support to Participating Contractors during [insert time periods] |
|  | Liaise between patients and contractors every [insert time frame] to ensure holistic care  Advise the Lead Pharmacist of any necessary changes to the Service. |
| 5 | Scope of SLA |
|  | SLA will be effective from [insert date] to [insert date] |
|  | Communication between DTS and Community Pharmacy |
|  | Detail communication lines between DTS and community pharmacy, identify lead from each party and provide contact details. |
|  | Contact with patient |
|  | Provide details of who is responsible for sending patient reminders, how many should be sent and time frames  Provide details of who is responsible for following up with the patient after appointment |
|  | Missed Appointments |
|  | Provide details of who is responsible for contacting patient if they failed to turn up for their appointment and how this should be managed |
| 6 | Withdrawal from SLA |
|  | Provide notice period for withdrawing from this service (both parties) |
| 7 | Renumeration & ordering of LAIB |
|  | Provide details of the ordering process into the pharmacy  Provide details for remuneration and administration fees (to be agreed between DTS, community pharmacy and payor) |
| 8 | Performance management & service quality |
|  | Add in KPIs agreed between each party and review period  This may be fortnightly catch ups to begin with to identify any teething problems and move to monthly, quarterly etc. |
| 9 | Confidentiality |
|  | Include local guidelines |
| 10 | Indemnity |
|  | Include local guidelines |
| 11 | Contact details & emergency contacts |
|  | Include local details |

**Appendix A**

**Referral for continuation of Buvidal treatment**

Dear [Pharmacy]

Patient name:

Date of birth:

This patient is suitable for treatment with Buvidalfor the treatment of opioid dependence.

Treatment was started on [date started] [dose].

If you agree to take on this patient, please undertake monitoring and treatment from [date].

If you are not able to take on this patient, please reply to [insert email address] by [date].

Next review with this department: [date]

You will be sent a written summary within 14 days. [Dr] at [DTS] is available to provide additional information should you require. The patient will continue to be managed by [staff name] at [DTS] for regular reviews along with social and psychological support while receiving Buvidal.

Thank you.

*Signature Date*

Consultant name

**Prescribing Information for Buvidal® (buprenorphine prolonged-release solution for injection)**

Please refer to the Summary of Product Characteristics (SmPC) before prescribing

**Active ingredient:** Buprenorphine. Prolonged-release solution for injection in pre-filled syringes. Weekly injection (8 mg, 16 mg, 24 mg, 32 mg) or monthly injection (64 mg, 96 mg, 128 mg, 160 mg).

**Indication:** Treatment of opioid dependence within a framework of medical, social and psychological treatment. Treatment is intended for use in adults and adolescents aged 16 years or over.

**Dosage:** To avoid precipitated withdrawal, initiate when objective and clear signs of mild to moderate withdrawal are evident, considering the duration of action of the opioid, time since last dose and degree of opioid dependence. Do not start until ≥6 hours after last heroin or short-acting opioid. Reduce methadone to ≤30 mg/day and start Buvidal® ≥24 hours after the last methadone dose. Buvidal®may trigger withdrawal symptoms in methadone-dependent patients. *Initiation in patients not already receiving buprenorphine:* Patients not previously exposed to buprenorphine, administer 4 mg sublingual buprenorphine and observe for an hour to confirm tolerability. Recommended starting dose of Buvidal® is 16 mg, with one or two additional 8 mg doses at least 1 day apart (target dose of 24 mg or 32 mg during the first week). The dose for the second week is the total dose administered during the first week. May transfer to monthly Buvidal® after four weeks and once stabilised. *Switching from sublingual buprenorphine*: Switch directly to weekly or monthly Buvidal®, starting on the day after the last sublingual buprenorphine dose. See SmPC for dose recommendations. *Maintenance:* Weekly or monthly as needed. One supplemental Buvidal® 8 mg dose may be administered between regular weekly or monthly doses (except 160mg). The maximum dose is 32 mg weekly, with an additional 8 mg dose, or 160mg monthly. *W*eekly doses may be administered up to 2 days before or after the weekly time point, and monthly doses may be administered up to 1 week before or after the monthly time point. If a dose is missed, administer the next dose as soon as practical. *Termination*: Consider prolonged-release characteristics and any withdrawal symptoms. If switching to sublingual buprenorphine, do so one week after the last weekly dose or one month after the last monthly dose of Buvidal®*. Elderly:* No dosing recommendations over 65 years. Consider renal and hepatic function*.*

**Administration**:Administration of Buvidal®is restricted to healthcare professionals only. For subcutaneous administration only. Inject slowly and completely into sufficient subcutaneous tissue of the buttock, thigh, abdomen, or upper arm area. Do not re-inject the same injection site for at least 8 weeks (each area can have multiple injection sites).

**Contraindications:** Hypersensitivity to buprenorphine or excipients. Severe respiratory insufficiency. Severe hepatic impairment. Acute alcoholism or *delirium tremens.*

**Special warnings and precautions for use:** Must not be administered intravenously, intramuscularly or intradermally. Monitor for any attempts to remove the depot. Some precautions associated with buprenorphine class. *Prolonged-release properties* of the product should be considered during treatment. Patients with concomitant medicines and/or co-morbidities should be monitored for signs and symptoms of toxicity, overdose or withdrawal. *Respiratory depression:* Deaths reported with buprenorphine. Care in respiratory insufficiency. *CNS depression:* Buprenorphine may cause drowsiness. *Dependence:* Chronic administration of buprenorphine can produce opioid dependence. *Serotonin syndrome:* Concomitant serotonergic agents (e.g. monoamine oxidase inhibitors, selective serotonin re-uptake inhibitors, serotonin and noradrenaline re-uptake inhibitors or tricyclic antidepressants) may result in serotonin syndrome, a potentially life-threatening condition - if clinically warranted, observe carefully, particularly during initiation and dose increases and consider reducing or discontinuing therapy if serotonin syndrome is suspected. *Hepatitis, hepatic events and hepatic impairment:* Recording of baseline liver function tests and viral hepatitis status recommended. Hepatic injury reported with buprenorphine. Caution with buprenorphine in moderate hepatic impairment – monitor for signs and symptoms of opioid withdrawal, toxicity and overdose. Monitor hepatic function regularly. *Drug withdrawal syndrome (GB):* Before starting any opioids, discuss withdrawal strategy with the patient. Dose tapering over weeks or months may be required. Risk of neonatal withdrawal syndrome following use in pregnancy. *Precipitation of opioid withdrawal syndrome:* Buprenorphine products have precipitated withdrawal symptoms in opioid-dependent patients when administered before the agonist effects from recent opioid use or misuse have subsided. *Renal impairment:* Caution in severe renal impairment. *QT-prolongation:* Caution with other medicines that prolong the QT interval and in patients with a history of long QT syndrome or other risk factors for QT prolongation. *Acute pain management:* A combination of opioids with high mu-opioid receptor affinity, non-opioid analgesics and regional anaesthesia might be necessary. Monitor and titrate, considering potential risk of overdose and/or death. *Sleep-related breathing disorders:* Opioids can cause sleep-related breathing disorders. *Opioid class effects:* See SmPC for details. *Interactions*:See SmPC for buprenorphine interactions. *Pregnancy and lactation*:Caution – see SmPC for details. *Driving and operating machines:*Minor to moderate influence, including drowsiness, dizziness or impaired thinking – likely to be pronounced by alcohol or CNS depressants. See SmPC for details of what individual patients should be told by the prescriber.

**Undesirable effects:** *Very common:* insomnia, headache, nausea, hyperhidrosis, drug withdrawal syndrome, pain. *Common:* infection, influenza, pharyngitis, rhinitis, lymphadenopathy, hypersensitivity, decreased appetite, anxiety, agitation, depression, hostility, nervousness, abnormal thinking, paranoia, medical dependence, somnolence, dizziness, migraine, paraesthesia, syncope, tremor, hypertonia, speech disorders, lacrimal disorder, mydriasis, miosis, palpitations, vasodilation, hypotension, cough, dyspnoea, yawning, asthma, bronchitis, constipation, vomiting, abdominal pain, flatulence, dyspepsia, dry mouth, diarrhoea, gastrointestinal disorder, rash, pruritus, urticaria, arthralgia, back pain, myalgia, muscle spasms, neck pain, bone pain, dysmenorrhea, injection site reactions (pain, pruritus, erythema, swelling, reaction, induration, mass), peripheral oedema, asthenia, malaise, pyrexia, chills, neonatal withdrawal syndrome, chest pain, abnormal liver function tests. *Other:* urinary retention, injection site reactions (abscess, ulceration and necrosis). See SmPC for further details.

**Overdose:** Apply general supportive measures, closely monitoring and treating respiratory and cardiac status. Consider long duration of action of buprenorphine and prolonged release from the depot.

**Package quantities and UK net price:** 1 pre-filled syringe per pack. Weekly injection (8 mg (0.16 ml), 16 mg (0.32 ml), 24 mg (0.48 ml), 32 mg (0.64 ml)): £55.93. Monthly injection (64 mg (0.18 ml), 96 mg (0.27 ml), 128 mg (0.36 ml), 160 mg (0.45 ml)): £239.70. **Marketing authorisation numbers:** *GB:* PLGB 42800/0001, PLGB 42800/0003-9. **ROI and NI:** EU/1/18/1336/001-7, EU/1/18/1336/009. **Legal category:** POM. **Marketing authorisation holder:** Camurus AB, Ideon Science Park, SE-223 70 Lund, Sweden. Email: [Camurus.uk@camurus.com](mailto:Camurus.uk@camurus.com) Additional information available on request.

**Date of revision:** May 2024FPI-0008

**Adverse events should be reported. Reporting forms and information can be found at** [**www.mhra.gov.uk/yellowcard**](http://www.mhra.gov.uk/yellowcard) **(or search for MHRA Yellow Card in the Google Play or Apple App Store) for the UK and** [**http://www.hpra.ie/homepage/about-us/report-an-issue**](http://www.hpra.ie/homepage/about-us/report-an-issue) **for Ireland. Adverse events should also be reported to Camurus AB via email:** [**safety@camurus.com**](mailto:safety@camurus.com)