

COVID-19

Guidance for the use of Buvidal for Opiate Substitution Treatment in Prisons during the Covid-19 Pandemic



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Further Information

For more information on COVID see the COVID guidance section of our website, www.gov.scot/coronavirus.

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The following guidance has been developed utilising a template produced by colleagues in NHS Wales. The authors of this document wish to express their gratitude to the following clinicians for sharing their work and permitting elements of this to be incorporated into this guidance:

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1. Executive Summary

The Covid-19 pandemic has placed unprecedented pressures on health and social care settings, including prisons.

Staff absence due to Covid-19 illness, self-isolation or caring for sick dependants, combined with an increased burden of ill health among people in these settings, compromises the ability to maintain normal operations.

In such circumstances it is important that all appropriate steps are taken to reduce the routes for transmission of infection in establishments where modelling predicts significant infectivity rates due to closed conditions and close proximity of people.

In February 2020 a snapshot of opiate substitution treatment (OST) provided to people in prison showed that, on a day when the prison population was 8005, OST was being provided to 2051 people (25.6% of the population). OST is administered daily under supervision and, based on these figures, there are 14,357 interactions per week between patients and staff for this treatment alone. OST provided by this model has the potential to facilitate the spread of infection in prisons, placing clinicians and patients at risk. In addition, this model requires significant nursing resource to deliver a medicines' administration process. This nursing resource, which is likely to be depleted, may be better directed to other patient centred interventions.

Buvidal is a depot formulation of buprenorphine that has been accepted for use (restricted) in NHS Scotland by the Scottish Medicines Consortium (SMC)¹

Buvidal allows for patients to be quickly and safely initiated onto monthly subcutaneous injections, minimising their contacts with frontline healthcare staff, whilst still receiving OST for their dependency. Benefits of Buvidal include dose stabilisation, which blocks on-top use, an improved quality of life for patients and safety from opiate related overdose.

This document offers guidance to assist in the immediate implementation of a new clinically proven method of OST, Buvidal, to meet patient treatment needs and reduce the burden of daily OST provision in NHS Scotland and Scottish Prison Service during the COVID-19 pandemic.

¹ <https://www.scottishmedicines.org.uk/medicines-advice/buprenorphine-buvidal-full-smc2169/>

2. Clinical Considerations for Implementing Buvidal Treatment in a Covid-19 Pandemic

These guidelines have been written to be adaptable to individual patient requirements, allowing clinicians to offer patient centred interventions in difficult circumstances.

There is now a need, in the Covid-19 Pandemic, to transfer appropriate patients in prison receiving daily OST via oral methadone or solid dose buprenorphine to monthly injections of slow-release buprenorphine (Buvidal) in order to:

- Provide safe and continuous management of dependency in a group at high risk of developing Covid-19 infection, severe disease and at high risk of transmitting the infection to others.
- To proactively ensure the continuity of OST in prison settings affected by Covid-19.
- Achieve a rapid reduction in the need for daily contact with NHS front line and SPS staff, releasing these resources for other duties.
- Reduce the risk of transmission of Covid-19 to other vulnerable patients in prisons.

3. Key Prescribing Issues for Buvidal during the Covid-19 Pandemic

Patients who can tolerate an 8mg oral dose of buprenorphine can be considered for transfer to Buvidal. For the purposes of this guidance only patients with at least 6 months of their sentence left to serve should be considered for transfer to Buvidal.

1. Buvidal can be administered by practitioners competent in subcutaneous injections, as it is only 0.5ml in volume and comes in a pre-filled safety syringe (which prevents post-injection needlestick injuries). Buvidal is a controlled drug (CD) and should be stored in a CD cupboard. During the Covid-19 pandemic, prompt transfer to the monthly injection is key.
2. Patients receiving oral buprenorphine (sublingual or Espranor) for more than a week, can transfer immediately to equivalent monthly preparation, usually monthly Buvidal 96mg (= ~16mg daily buprenorphine). Monthly doses can be given +/- 1 week, allowing significant flexibility during the pandemic.
3. Patients not currently receiving buprenorphine and who can tolerate an 8mg oral buprenorphine dose (without precipitated withdrawal), can have, within 1 hr of the oral dose, weekly Buvidal 16mg (= ~8-10mg daily buprenorphine). If 16mg weekly unavailable, can consider 8mg or 24mg dose.
Top up doses may be administered, if required, after 2-4 days (weekly 8mg Buvidal = ~4mg daily buprenorphine).
A week after the first weekly Buvidal dose, it is possible to give a monthly dose as above - monthly Buvidal 96mg (= ~16mg daily Buprenorphine). If 96mg monthly unavailable, can be 64mg or 128mg.
4. Flexible Dosing:
 - Doses: If certain doses are unavailable, it is possible to give the next closest one, higher or lower. e.g. no 96mg, can give 64mg or 128mg.
 - Timings: can give next week's +/- 2 days, monthly, can give +/- 1 week.

5. Drop Outs: If patients drop out of treatment, the Buvidal effect dissipates slowly and will protect against accidental overdoses. Buvidal is likely to take between one week and 2-3 months to 'wear out', depending on last dose and previous amount taken.
6. Pain issues: Addressed as in oral treatment i.e. may need higher full agonist doses / alternative pain relief.

4. Introduction: Use of Buvidal in the Covid-19 Pandemic

The Covid-19 pandemic is presenting unprecedented public health, health service and societal challenges. The current aims of the delay phase are to institute interventions to try to reduce the risk of transmission within the population, especially among vulnerable groups (both to the effects of Covid-19 and onward transmission within the group) and to reduce the non-urgent demand for health care services.

4.1 Buvidal: Brief Overview of Current Clinical Use

Buvidal, developed by Camurus, is a new slow release formulation of buprenorphine available in 7 or 28 day depot injections. This product is supplied as a single use pre-filled 0.5ml sub-cutaneous injection and is delivered in a similar manner to many vaccines.

Buvidal has been reviewed by SMC and approved for use (restricted) in Scotland. The slow release injection is already in use in both Drug and Alcohol Specialist Services and GP services in some areas of NHS Greater Glasgow and Clyde and NHS Lanarkshire, though its adoption has been limited to date. Where it is currently used in Europe and Australia, it has been shown that:

- Transition from oral buprenorphine is very simple; just a switch to injectable form
- The injection being only 0.5 ml is very well tolerated
- Patients report improved quality of life especially not having to attend for daily supervised oral treatments
- Although approximately 1 in 4 opiate users in any treatment will use illicit heroin at times, there are no risks associated with patients/clients on prolonged-release buprenorphine solution, due to its blockading effect (similar to oral buprenorphine; at higher effective doses it prevents heroin and other full agonist opioids from having significant effects on, for example, respiratory depression)².

² Frost, M., et al. Long-term safety of a weekly and monthly subcutaneous buprenorphine depot (CAM2038) in the treatment of adult out-patients with opioid use disorder. *Addiction*. 2019;114(8):1416-1426; 3. <https://onlinelibrary.wiley.com/doi/full/10.1111/add.14636>

- Buvidal's safety profile is consistent with oral buprenorphine, with the exception of mild-to-moderate injection site adverse reactions ³.
- The injectable formulation can be given by any health care professional trained in subcutaneous injection. The pre-filled syringe has numerous safety features to prevent re-use/diversion/needle-stick injuries. It has a long shelf life of approximately two years and does not require refrigeration.

4.2 Which Patients/Clients are Suitable to be Switched and can be Switched?

In August 2019 the SMC approved Buvidal for use (restricted) in patients for whom methadone is not suitable and for whom the use of buprenorphine is considered appropriate. In the current pandemic situation, daily OST with methadone is not considered to be a suitable treatment.

4.3 Transferring to Buvidal from Alternative Buprenorphine Prescription

In practice, it is simplest to switch those already on other forms of buprenorphine to Buvidal. The clinical experience, both from the clinical trials and routine prescribing, shows the feasibility of simply switching to the monthly equivalent dose immediately and therefore this approach is preferred, especially in the context of the pandemic.

4.4 Initiating Buvidal When Not in Treatment (on Heroin or Lapsed from Methadone Treatment)

For patients new to treatment or those who have missed doses and are re-starting, the process is extended as follows:

- They have an initiation dose of 8mg oral buprenorphine.
- Once tolerance to buprenorphine is established and signs of precipitated withdrawal are absent (usually clear from 30min to 1 hour after dose) a weekly dose of Buvidal can be administered (usually 16mg of weekly Buvidal ~8mg daily buprenorphine).

³ Ibid

- Patients can then progress to the monthly dose-equivalent the week after (usually 96mg of monthly Buvidal \approx 16mg daily)

4.5 Transferring to Buvidal from Methadone Treatment

It will be possible to plan transfers from methadone to Buvidal in a relatively straightforward manner. This is similar to transferring patients from methadone to oral buprenorphine. There will have to be an arranged dose reduction of methadone and a break from use to establish withdrawal, followed by an initiation dose of 8mg of oral Buprenorphine as above (see section 7.0 for detailed guidance).

5. Protocol to Reduce Covid-19 Transmission Risks and Sustain Treatment System in the Current Pandemic Using Buvidal

5.1 Criteria for Prescribing Buvidal During Covid-19 Pandemic

Patients who can tolerate 8mg of buprenorphine can be considered for transfer to Buvidal. For the purposes of this guidance only people with at least 6 months of their sentence left to serve should be considered for transfer to Buvidal.

In addition, transfer to Buvidal should occur as follows:

- Those currently receiving an alternative buprenorphine product should transfer as soon as possible to Buvidal.
- A phased approach should then be adopted to transfer patients in receipt of methadone to Buvidal (e.g. one half at a time)

The following groups of people in prison should not be considered for transfer to Buvidal:

- Those on remand.
- Those with less than 6 months of their sentence left to serve.

It is proposed that these groups be excluded from the protocol due to challenges associated with arranging through care and the possibility of multiple changes to treatment in a short period of time.

Buvidal should be considered for patients where there is a diagnosis of opioid dependency, based on history, examination and investigations. Its indication is not reserved for any specific subgroup of opioid dependent patients.

Prior to prescribing Buvidal during the Covid-19 pandemic the clinician/prescriber should complete as full an assessment as possible, given the local circumstances, in much the same way as if they were starting oral buprenorphine treatment. In effect:

- A specialist addiction assessment has been completed, as much as is possible in the context of the Covid-19 pandemic, with, ideally,

evidence of opioid dependence through history, examination and appropriate drug screening tests.

- In the context of the Covid-19 pandemic, this patient would benefit from being on Buvidal.
- The patient has been provided with comprehensive information concerning the potential benefits and risks of Buvidal, including side effects and hazards (the company patient leaflet covers this) and has agreed to a prescription of Buvidal.
- Although baseline liver function tests are recommended prior to commencing buprenorphine treatment they are not mandatory.
- Patients, particularly those transferring from methadone, should be advised that they may experience sleep disturbance, which will be temporary and resolve .

5.2 Exclusion Criteria for Buvidal

Buvidal is contraindicated in the following circumstances:

- Hypersensitivity to buprenorphine or to any excipients in Buvidal:
 - Soybean phosphatidylcholine, Glycerol dioleate, Ethanol anhydrous, N-Methylpyrrolidone
- Severe respiratory insufficiency
- Severe hepatic impairment
- Acute alcoholism or delirium tremens

5.3 Interactions with Other Medications

Interactions with other medications are the same for oral buprenorphine. No interaction studies have been conducted with Buvidal. Patients with concomitant medicinal products and/or comorbidities should be monitored for signs and symptoms of toxicity, overdose or withdrawal caused by increased or decreased levels of buprenorphine.

Buprenorphine should be used with caution if co-administered with:

- Sedating agents such as Benzodiazepines, Gabapentinoids, Alcohol, CNS depressants
- Opioid analgesics- opioid analgesics should be discontinued prior to initiating Buvidal treatment and alternative analgesia prescribed, which should not be a gabapentinoids.

- Opioid antagonists: naltrexone and nalmeferene
- Monoamine oxidase inhibitors
- CYP3A4 inhibitors and inducers

Clinicians should report adverse drug reactions associated with Buvidal treatment through the established Yellow Card system; as they would with any suspected drug reaction.

6. Procedure for Buvidal Treatment and Dosing Induction

The clinician should explain the principle of prolonged-release medication and how it differs from oral buprenorphine or methadone. The clinician should explain that administration will involve a subcutaneous injection (under the skin) which will be administered either initially weekly then monthly or immediately monthly in the context of the Covid-19 pandemic. They should also explain potential side effects (which are the same as oral buprenorphine) but with the additional injection site reactions.

To avoid precipitating symptoms of withdrawal, treatment with Buvidal should be started when objective and clear signs of mild to moderate withdrawal are evident, which the patient should be made aware of. Consideration should be given to the type of opioid used prior to commencing Buvidal (that is long- or short-acting opioid). Although there may be individual variation, Buvidal should not be administered until the following length of time since the last dose/use of opioid:

Patient's current opioid	Length of time since last dose of opioid
Heroin	At least 6 hours
Methadone (dose <30 mg)	At least 24 hours
Buprenorphine	The day after their last dose
Opioid medication	Dependant on medicine and formulation

6.1 Treatment with Monthly Buvidal

Treatment with monthly Buvidal can be started once patients have been stabilised on weekly treatment (at least one week). In the case of the Covid-19 pandemic, it makes sense for the majority to transition to monthly as soon as possible.

6.2 Administration of Buvidal

Administration is restricted to healthcare professionals competent in subcutaneous injection techniques. Appropriate precautions, such as conducting patient follow-up visits with clinical monitoring according to the patient's needs, should be taken into account when prescribing and administering Buvidal. Take-home use or self-administration of the product by patients is not allowed.

7. Initiating Buvidal Treatment for Patients in Prison

Please see Appendix 1 for the “Buvidal Dosing Table”

Prior to initiating Buvidal Treatment, Local NHS Health Boards and SPS Senior Management will have agreed a plan for implementation.

Consent will be sought from those moving to Buvidal to allow this information to be shared with SPS. This would allow Prison Officers to monitor for any signs of an adverse reaction. When seeking consent it will be made clear to the patient this is on a voluntary basis and that, by doing so, their confidentiality may be compromised.

7.1 Initiation of Buprenorphine Naïve Patients Not Currently Receiving OST

Buprenorphine naïve patients must be in established withdrawals prior to commencing any buprenorphine based treatments. It is recommended that clinicians use an objective assessment of withdrawal, such as COWS or SOWS, to establish withdrawal and the patient sign to confirm their response to the questionnaire. (N.B. Benzodiazepines can mask objective withdrawal scoring)

Once in established withdrawals the patient should be given a single 8mg oral dose of buprenorphine and observed for 1 hour to confirm tolerability of the drug.

The following day, assuming no intolerance, the patient should be given a 16mg seven day depot injection of Buvidal.

Should this be insufficient for the patient’s requirements an additional one or two supplemental doses of 8mg depot injections can be administered. These must be administered at least one day apart, if required, (especially in the titration stage) to achieve the target dose of 24 mg or 32 mg during the first treatment week.

The 2nd week’s injection dosage will be 16mg + total of “top up” doses. There should be no need for top up doses in week 2.

Treatment with monthly Buvidal can be started after treatment initiation with weekly Buvidal, in accordance with the dose conversion in Table 1 and once patients have received 2 weekly treatments.

Table 1: Conversion table from weekly to 4 weekly administration formulations of long acting SC buprenorphine

Weekly dose	4 weekly dose
16mg	64mg
24mg	96mg
32mg	128mg

7.2 Transferring Patients to Buvidal From an Alternative Buprenorphine Treatment

Patients currently treated with oral buprenorphine may be switched directly to monthly Buvidal, starting on the day after the last daily oral buprenorphine treatment dose. No withdrawal symptoms should be displayed. Table 2 contains the expected conversion information from oral daily doses to long acting buprenorphine SC injection.

Table 2: Conversion table from oral buprenorphine to weekly and 4 weekly administration formulations of long acting SC buprenorphine

Daily dose oral buprenorphine*	Weekly dose of long acting SC buprenorphine	4 weekly dose of long acting SC buprenorphine
2-6mg	8mg	
8-10mg	16mg	64mg
12-16mg	24mg	96mg
18-24mg	32mg	128mg

*The dose of buprenorphine in mg can differ between oral products, with the oro-dispersible formulation having a higher, initial bioavailability. There is little evidence that this is clinically significant, so treat all oral formulations of buprenorphine as dose equivalent.

7.3 Transferring Patients to Buprenorphine From Methadone

7.3.1 Patients Receiving up to 50mg of Methadone Daily.

Clinical experience has demonstrated that methadone should be reduced to a maximum of 50mg per day prior to starting Buprenorphine treatment. This differs from the Summary of Product Characteristics recommendation of 30 mg.

Buprenorphine naïve patients must be in established withdrawal prior to treatment with a buprenorphine product.

Methadone treatment must be terminated and the patient reviewed daily for signs of established withdrawal. Withdrawal should be confirmed using an objective assessment tool such as COWS or SOWS and the patient asked to sign the questionnaire to confirm their responses. (N.B. Benzodiazepines can mask objective withdrawal scoring)

Once in established withdrawal the patient should be given a single 8mg oral dose of buprenorphine and observed for 1 hour to confirm tolerability of the drug.

The following day, assuming no intolerance, the patient should be given a 24mg seven day depot injection of Buprenorphine.

Should this be insufficient for the patient's requirements an additional one or two supplemental doses of 8mg depot injections can be administered. These must be administered at least one day apart, if required (especially in the titration stage), to achieve the target dose of 32 mg or 40 mg during the first treatment week.

The 2nd week's injection dosage will be 24mg + total of "top up" doses. There should be no need for top up doses in week 2.

In week 3 administer the first monthly injection of Buprenorphine, the dose being determined by the conversion chart. (Table 2)

7.3.2 Patients Receiving Greater than 50mg of Methadone Daily
Patients receiving doses greater than 50mg of methadone can also be transferred directly to Buvidal, as high dose transfers from methadone to buprenorphine have been shown to be readily achievable in clinic settings⁴.
⁵.

Buprenorphine naïve patients must be in established withdrawal prior to treatment with a buprenorphine product.

Methadone treatment must be terminated and the patient reviewed daily for signs of established withdrawal. Withdrawal should be confirmed using an objective assessment tool such as COWS or SOWS and the patient asked to sign the questionnaire to confirm their responses. (N.B. Benzodiazepines can mask objective withdrawal scoring).

The onset of established withdrawals are subject to patient variability, but should not be anticipated within 36 hours of methadone termination. Those in receipt of higher doses of methadone may take longer to establish withdrawal.

Once in established withdrawals the patient should be given an 8mg oral dose of buprenorphine and observed for 1 hour to confirm tolerability of the drug. Assuming the patient is tolerant of buprenorphine then an additional 8 mg oral dose of buprenorphine should be given.

The following day, assuming no intolerance, the patient should be given a 24mg seven day depot injection of Buvidal. Should this be insufficient for the patient's requirements an additional supplemental dose of an 8mg depot injection can be administered to achieve the target dose of 24 mg or 32 mg during the first treatment week. Where clinically indicated a further 8mg depot injection may be administered bringing the first week treatment dose to 40mg. All supplemental doses must be administered at least one a day part.

⁴ Hill, D & Conroy, S., (2014). Case note review – Transfer of patient to buprenorphine from daily doses of methadone greater than 30mg. *Heroin Addiction and Related Clinical Problems*. 2014. 16 (1). 55 - 64

⁵ Conroy, S. & Hill, D. (2013). Transfer to buprenorphine from daily doses of methadone greater than 30mg – initial review of transfers. *Heroin Addiction and Related Clinical Problems*. 2013 15 (3); 19 - 28

The 2nd week's injection dosage will be 24mg + total of "top up" doses.
There should be no need for top up doses in week 2.

In week 3 administer the first monthly injection of Buvidal, the dose being determined by the conversion chart. (Table 2)

8. Administration

Buvidal is administered by a sub-cutaneous injection in 4 regions on both sides of the body; upper arm, abdomen (not close to umbilicus), buttocks and thigh.

Pinch the skin prior to administration then the injection is made at 90 degrees to the skin surface. The plunger should be slowly depressed. Once the full dose has been administered, wait for 10 seconds before starting to remove the syringe (with the plunger still fully depressed) gradually. Once fully removed, the plunger can be released and the needle will retract into the syringe barrel and the device should be disposed of in a sharps container.

It is important that the recording of the administration specifies which site has been used and which side of the body.

9. Maintenance Treatment and Dose Adjustments

Buvidal can be administered weekly or monthly. Doses may be increased or decreased and patients can be switched between weekly and monthly products according to individual patient's needs and treating physician's clinical judgement as per recommendations in Table 1. Following switching, patients may need closer monitoring.

9.1 Supplemental Dosing Once on Maintenance Treatment

A maximum of one supplemental Buvidal 8 mg dose may be administered at an unscheduled visit between regular weekly and monthly doses, based on individual patient's temporary needs.

The maximum dose per week for patients who are on weekly Buvidal treatment is 32 mg with an additional 8 mg dose.

The maximum dose per month for patients who are on monthly Buvidal treatment is 128 mg with an additional 8 mg dose.

10. Missed Doses

To avoid missed doses, weekly dose may be administered up to 2 days before or after the weekly time point and monthly dose may be administered up to 1 week before or after the monthly time point.

If a dose is missed, the next dose should be administered as soon as practically possible.

11. Termination of Treatment

If Buvidal treatment is discontinued, its prolonged-release characteristics and any withdrawal symptoms experienced by the patient must be considered. If the patient is switched to treatment with oral buprenorphine, this should be done one week after the last weekly dose or one month after the last monthly dose of Buvidal according to the recommendations in table 2.

12. Transfer from Long Acting Buprenorphine to Normal Oral Formulation of OST

For patients returning to treatment with oral buprenorphine products, recommence the oral formulation at the dose from the corresponding Buvidal dose (Table 2). The oral formulation should be recommenced on the date the next Buvidal dose was expected to be administered. The dose should be assessed after 7 days and following patient assessment adjusted accordingly in response to the clinical presentation and patient need.

For patients returning to treatment with methadone, the oral methadone should be commenced at 30mg on the date the next Buvidal dose was expected to be administered. The dose should then be titrated as per local policy adjusting in response to clinical presentation and patient need.

13. Evaluation of Use of Buprenorphine

The use of Buprenorphine in custodial settings will be evaluated using the objectives and measures set out in Table 3 below.

Table 3

Objective	Measure
<p>To ensure continuity of OST provision to people in prison during the COVID-19 pandemic.</p> <p>To compare the time and cost associated with administration of buprenorphine compared to other forms of OST in custodial settings.</p>	<p>1. Staff contact time spent on administration of Buprenorphine (in minutes per day/week):-</p> <ul style="list-style-type: none"> • Prison healthcare staff • SPS staff <p>2. Number of people moved to Buprenorphine from:-</p> <ul style="list-style-type: none"> • Methadone • Buprenorphine • Espranor • Suboxone <p>3. Percentage of total number on OST within each prison switched to Buprenorphine.</p>
<p>To examine patient satisfaction and experiences of treatment with Buprenorphine compared to other forms of OST.</p>	<p>Number and percentage of people successfully switched from other OST and maintained on Buprenorphine (after one month).</p>
<p>To identify any unexpected safety and tolerability considerations of Buprenorphine specific to the adult custodial population with moderate to severe opioid use disorder.</p>	<p>1. Retention rate as above.</p> <p>2. Number of reported adverse reactions / tolerability issues (and as percentage of total number switched per prison).</p>
<p>To assess diversion and other non-medical use of Buprenorphine and impact of these activities on risk of violence compared to other forms of OST in custodial settings.</p>	<p>1. Number of reported incidents of diversion.</p> <p>2. Number of reported incidents of bullying and intimidation related to OST (and percentage increase / decrease since switch to Buprenorphine).</p>

	<ol style="list-style-type: none">3. Number of incidents of prisoner to prisoner and prisoner to staff violence4. Number of cases of people under the influence of illicit substances.
To assess staff satisfaction and acceptability	<ol style="list-style-type: none">1. All of the above.2. Qualitative feedback from staff.

APPENDIX 1- BUVIDAL DOSING GUIDANCE TABLE

Daily dose oral buprenorphine*	Weekly dose of long acting SC buprenorphine	4 weekly dose of long acting SC buprenorphine
2-6mg	8mg	
8-10mg	16mg	64mg
12-16mg	24mg	96mg
18-24mg	32mg	128mg

APPENDIX 2 – USEFUL CONTACTS

Thomas Byrne (National Prisons Pharmacy Adviser, Health Improvement Scotland) – ThomasByrne@nhs.net

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