

A call to action

Modernising pathways of care for patients with hepatitis C: Overcoming barriers to allow treatment in community pharmacies

By the London Joint Working Group on Substance Use and Hepatitis C

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Introduction

The NHS is committed to supporting patients with hepatitis C with a strategic aim to eliminate the disease ahead of World Health Organisation goals as detailed within the NHS Operational planning and contracting guidance 2019/20¹ and NHS the Long-Term Plan.² Through the Long-Term Plan and move to Integrated Care Systems the NHS is also committed to the introduction of new service models which are innovative, patient centered and integrated.

Fully embracing these strategic priorities and ambitions, the London Joint Working Group have been exploring the options around the introduction of a community pharmacy hepatitis C treatment service. Despite full local system support for the initiative and examples of similar services being introduced successfully in Scotland, the work has come to an impasse due to the legislation, bureaucracy and overly complex processes associated with the commissioning of High Cost Non-National Tariff drugs.

This paper outlines the barriers to the implementation of a truly integrated and patient centered service and is aimed at stimulating debate in-order to influence legislative and commissioning change and reform.

Background

Current commissioning of hepatitis C drugs

NHS England is the responsible commissioner for high cost excluded drugs in hepatitis C³, there are currently Patient Access Scheme Prices associated with NICE Technology Appraisals of these medicines. Currently due to legislation hospital providers need to invoice NHSE on an individual patient level for excluded drugs to be funded from the NHSE specialist drug budget.

¹ NHS Operational planning and contracting guidance 2019/20 NHS Improvement January 2019 <https://www.england.nhs.uk/wp-content/uploads/2018/12/nhs-operational-planning-and-contracting-guidance.pdf>

² NHS Long Term Plan, NHS England January 2019 <https://www.longtermplan.nhs.uk/>

³ Specialised Commissioning <https://www.england.nhs.uk/commissioning/spec-services/>

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All providers have been mandated since 2016/17 to use Blueteq the standard electronic contractual prior approval process for high cost drugs and specialised services.⁴ At the point of prescribing providers of hepatitis C drugs are required to complete an application for funding prior to dispensing. This application triggers the payment approval process. Drugs prescribed that bypass this system will **not** be funded by NHSE.

Current legislation and regulation as a consequence of Hackett⁵ only allows hepatitis C drugs to be dispensed within a hospital pharmacy or via a provider contracted homecare service to a patient's fixed address or collection point. There is no current mechanism in place that allows the dispensing of hepatitis C drugs outside of these arrangements.

The London Joint Working Group has explored the options of a community pharmacy and home care delivery model.

Our preferred model is one in which patients would be able to collect their treatment from a named community pharmacy by direct dispensing or as an alternative via a home delivery service with a community pharmacy being the fixed collection point. The issues and barriers to these options are detailed in the following section.

Moving to a community pharmacy as a fixed collection point dispensing model

Issues and barriers

- Current legislation does not allow for community pharmacy to be reimbursed for NHSE funded drugs through either FP10 or HPFP10.
- Current commissioning and procurement arrangements preclude community pharmacies from purchasing high cost drugs at Patient Access Scheme Prices.
- Current prescribing arrangements mean that any high cost drug must be initiated through a secondary care provider. The subsequent dispensing via a community pharmacy would be classified as 'Secondary Dispensing' where medicines are dispensed at one pharmacy but supplied to the patient by a different pharmacy.

⁴ Improving Value for Patients from Specialised Care Commissioning Intentions 2016/2017 for Prescribed specialised Services <https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/09/comms->

⁵ Homecare Medicines, Towards a vision for the future DH Nov 2011. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/213112/111201-Homecare-Medicines-Towards-a-Vision-for-the-Future2.pdf

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- Secondary dispensing of medicines is strongly discouraged and supply of any medicines by means of secondary dispensing raises a number of issues/concerns as highlighted below (this should not be seen as an exhaustive list):
 - Patient consent must be obtained prior to engaging in any secondary dispensing activity;
 - The original prescription is usually retained by the dispensing pharmacy and therefore the second pharmacy (receiving the medicines for onward supply to the patient) may be unable to check and validate the prescription before handing the medicines over to the patient – this raises clinical and professional concerns about patient safety;
 - Without sight of the original prescription there is a potential risk for errors made at the dispensing pharmacy to be carried forward by the second pharmacy
 - It is a legal requirement for patients to receive medicines which have been labelled by the dispensing pharmacy;
 - Without sight of the original prescription and corresponding patient details (due to patient confidentiality reasons), errors may occur with validation during the handing out process at the second pharmacy.
 - If the dispensed item is supplied to the second pharmacy in a sealed bag the pharmacist cannot be certain of its contents before supplying the bag to a patient; the sealed bag cannot be opened by a pharmacist without patient consent;
 - The pharmacist at the second pharmacy will need to be satisfied that the medicines have been stored appropriately during transit and ensure that any special storage requirements are met at the pharmacy, for example, where cold-chain products are involved;
 - It may be unclear who is liable for any medicines that are lost or damaged during transit;
 - Responsibility for providing the patient with any technical and/or clinical advice should be determined prior to engaging in such a scheme;
 - Liability for any dispensing errors is considered on a case-by-case basis — the responsibilities and liabilities of each party should be discussed and agreed before entering into any agreement to offer secondary dispensing;
 - SOPs must be in place in an attempt to minimise the above risks and to ensure that the responsibilities of each party are clear.

Moving to a community pharmacy via homecare delivery as a fixed-point model Issues and barriers

- Current legislation and regulations prohibit the use of homecare if patients do not have a fixed address or collection point.
- Whilst collection points could be a named GP surgery or post office this does not come without significant risk i.e. patient confidentiality and drug wastage etc. This is not seen as a sustainable universal coverage solution.
- The pharmacist on duty is responsible for all medicines given out at that pharmacy. However, because the drug would have originally been dispensed by the Homecare provider, the medicine would be dispensed via secondary prescribing by that pharmacy, with the 'end dispensing pharmacist' unable to assume responsibility.

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- While there are provisions in the Human Medicines regulation regarding collection/delivery arrangements, Regulation 248 of The Human Medicines Regulations 2012 ⁶ states that where such a collection/delivery arrangement is implemented, the collecting point must be a premises which is **not a registered pharmacy**.
- Current legislation prohibits a collection point being a community pharmacy as the pharmacist on duty is responsible for all medicines given out at that pharmacy. However, because the drug would have originally been dispensed by the homecare provider, the medicine would be dispensed via secondary prescribing by that pharmacy, with the 'end dispensing pharmacist' unable to assume responsibility.
- Current arrangements for reclaiming VAT and being charged at Patient Access Scheme rates via the Homecare would be revoked if they were using a community pharmacy as the fixed address or collection point. This would result in the service being ultra vires to the terms of NHSE contract arrangements.

The LJWG has also explored other options:

Patient Group Directions

The use of PGD's is not an option due to the governance issues detailed in this paper.

Current examples and potential short-term solutions.

The LJWG also looked at other examples across England where high cost drugs have been dispensed outside of the main framework. Whilst there are initiatives in place, they are time consuming requiring micromanagement and are not deemed to be sustainable at scale.

Examples

HIV services in Hampshire:

With a similar patient group i.e. transient with no fixed address NHS Hampshire have for a small number of patients < 100, use churches or GP practices as collection points. This model is not seen as sustainable at scale in the longer term.

Osteoporosis:

Amgen matched the patient access scheme price in primary care to allow dispensing of denosumab in the community pharmacy. A similar option for hepatitis C would cut across current drug procurement processes.

Potential short-term solution

Delivery through Homecare to a designated collection point therefore providing access in primary care.

Whilst these examples indicate that there is scope for the modernisation of Hepatitis C pathways they merely overcome some of the issues relating to the commissioning of drugs by NHSE and do not allow for a long-term sustained solution.

⁶Human Medicines Regulations 2012 <http://www.legislation.gov.uk/uksi/2012/1916/contents/made>

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Next Steps

To move forward a change is needed in the commissioning and legal frameworks relating to the dispensing of high cost drugs. This will allow the fundamental redesign of patient pathways and patients will be able to access treatment in all settings including tertiary, secondary and community care. These changes will also mean that there will be no differential pricing. There is a need to lobby for a change in legislation to allow NHS England's long-term plan of the elimination of hepatitis C ahead of the WHO target to be realised.

As we move to a system of Integrated Care, we will see changes to the flow of financial resources at local and national level. Whilst this will overcome some of the issues relating to the invoicing for high cost excluded drugs, it will not change the legislative challenges surrounding community pharmacy or the governance arrangements surrounding NHSE as responsible commissioner.

A key objective of the Long-Term Plan is to move to a new service model in which patient get more options, better support and properly joined up care at the right time in the optimal care setting. This vision should not just be for non-specialist care but should cross all clinical disease areas and conditions.

If we are finally to dissolve the historical divides between primary, secondary and community services and are genuine in our intent to modernise all aspects of care, not just elements of them, we need to change the **system, regulations and legislative framework**.

Only by these supportive changes which will allow the establishment of non-acute models of care for patients with hepatitis C will we see the Long-Term Plan ambition realised.

Call to Action

The LJWG calls for the Department of Health and Social Care and NHS England to facilitate the delivery of prescriptions of hepatitis C treatments generated by secondary care through community pharmacies. We are disappointed that ongoing regulatory barriers to dispensing hepatitis C treatments in a community pharmacy setting continue. We previously highlighted this issue to the government and regulatory bodies to expand the delivery of hepatitis C testing and care in community pharmacies. We call for all stakeholders to rally behind finding a solution.

Contact info@ljwg.org.uk for more information