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South East Clinical Senate

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SE Region: Patient Support Programmes

Regional Principles for ‘value added schemes’

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SE Region: Patient Support Programmes – regional principles for ‘value added schemes’

This paper was prepared by the South East Clinical Senate and endorsed by the South East Regional Medicines Optimisation Committee. Its purpose is to:

- provide a brief overview of ‘Patient Support Programmes’ - a range of ‘value added services / value added schemes’ supported by the pharmaceutical industry; and
- specify certain key principles and governance arrangements to be applied within the Region.

The National Homecare Medicines Committee (NHMC) has previously published Good Practice Principles for Provision of Manufacturer Funded Homecare Medicines Services[1] and has drafted, but not yet published, a National Position Statement: ‘Manufacturer Funded Patient Support Programmes (PSPs) associated with a Homecare Service’ which describes in detail the clinical, operational, information and financial governance principles to be followed (Appendix A).

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[1] National Homecare Medicines Committee. Good Practice Principles: Provision of Manufacturer Funded Homecare Medicines Services. Published February 2018. Available from: https://www.sps.nhs.uk/wp-content/uploads/2018/03/NHMC-Good-Practice-Principles-Provision-of-Manufacturer-Funded-Homecare-....pdf

1. Introduction and Background

Patient support programmes (PSPs) are ‘value added services’ designed to provide tailored support to individual patients taking specific medicines, adding complementary value to medicinal products by supporting patient care.

PSPs have been defined as enhanced self-management support programmes that include interventions such as individualised medication counselling, training, support, and virtual reminders to improve medication-taking behaviour.[2] This definition encompasses a variety of patient-directed interventions, from educational programmes aimed at improving disease management, regardless of the patient’s treatment, to specific programmes that aim to provide education to patients and a follow-up on patients receiving a particular medicine. The European Medicines Agency has adopted a narrower definition for PSPs, recognising only organised systems in which a Marketing Authorisation Holder (MAH) receives and collects information relating to the use of its medicinal products.[3]

PSPs aim to provide solutions beyond the medication itself, by enhancing treatment adherence, improving clinical outcomes and patient experience, and increasing quality of life. PSPs are normally funded by pharmaceutical companies, but the service is delivered by a third party, so the pharmaceutical company has no direct contact with the patient. The services offered may vary, but can include:

- ensuring timely home delivery of patient medications
- training on effective self-medication and administration of medicines
- information on appropriate disease management pitched at a level suited to the patient
- motivational training to improve adherence to medication regimes
- telephone hotlines, including out of hours, to access advice from qualified healthcare professionals.

PSPs may be perceived by the clinical team as an opportunity to reduce pressure on parts of the service, while improving patient care. If they influence drug selection, however, they may result in additional cost to the service through selection of a less cost-effective medicine.

Pharmaceutical companies must work within the Association of the British Pharmaceutical Industry (ABPI) guidelines for patient safety and pharmacovigilance in PSPs.[4]

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[2] Ganguli A, Clewell J, Shillington AC. The impact of patient support programmes on adherence, clinical, humanistic, and economic patient outcomes: a targeted systematic review. Patient Prefer Adherence. 2016;10:711–25 PPA-101175-the-impact-of-patient-support-programs-on-adherence--clinica (dovepress.com) doi:10.2147/PPA.S101175

[3] European Medicines Agency. Guideline on good pharmacovigilance practices (GVP). Module VI: collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev 2). Vol. Revision 2. 2017

[4] Guidance notes for patient safety and pharmacovigilance in patient support programmes. ABPI Mar 2018 rmi-0103-0318-guidance-notes-for-patient-safety-and-pharmacovigilance-in-patient-support-programmes.pdf (abpi.org.uk)

2. Benefits and Disadvantages

There are over 15 million patients in the UK with long-term conditions, a key driver of the imperative to manage healthcare closer to the patient. A November 2018 briefing paper from the NHS Confederation highlighted that care for those with long-term conditions accounts for 55% of GP appointments, 68% of outpatient and A&E appointments and 77% of inpatient bed days.[5] PSPs enable self-management and potentially provide quality alternatives encouraging a number of healthcare providers and pharmaceutical companies to develop PSPs in an increasing diversity of disease areas.

Benefits of PSPs suggested by pharmaceutical companies are:

- Improved patient outcomes from better medication adherence, and overall disease management
- Patient safety. Patient monitoring may be provided, e.g. blood tests. Increased adverse reaction reporting to MHRA
- Ensuring a reliable supply chain leads to timely home delivery of patient medications
- PSPs come at no extra cost to NHS
- Reduces work for clinical team
- Patient feels supported with training on effective self-medication and administration of medicines, which can sometimes be complex
- May reduce overall costs to the healthcare system through reducing contacts with clinical team, GPs, A&E and hospital admissions
- Reduced contacts with healthcare settings during COVID pandemic.

There are also potential disadvantages to the NHS:

- One reason why the pharmaceutical company offers PSPs is to increase market share. PSPs increase patient enrolment and reduce switching between therapies.
- There is a potential risk that clinicians may opt for a more expensive drug which is linked with the PSP rather than a less expensive alternative, thereby increasing overall drug spend. This is particularly a concern if there are much cheaper but just as clinically effective drugs (e.g. biosimilars) approved for the same condition.
- The PSP is only available for patients prescribed a certain drug. This creates the potential for inequity of care between patients with the same condition but prescribed different drugs.
- Lack of communication between the different parts of the service is a known problem, with patients often not receiving a joined-up service.
- Financial benefits may not be shared across the system.
- As PSPs are provided by non-NHS bodies there are issues around sharing data, which has to be done with the patient's consent.
- PSPs are specific to the medication a patient has been prescribed and are therefore only available to patients while they are on certain medications, which may be restricted or just not favoured by some clinicians.

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[5] The value of patient support programmes, NHS Confederation, Briefing, November 2018, Issue 309

- If a patient needs to change to a different drug, they will no longer be able to access the additional support that they may have become used to, even if elements of the PSP offer would be useful at other points in their patient journey.

3. What does the published evidence tell us?

By and large the evidence supports many of the suggested benefits although surprisingly no study has highlighted sustainability and potential carbon-savings associated with PSPs. Meta-analysis of PSPs in inflammatory and immunological disorders[6] and a recent systematic review evaluating PSPs conducted in Europe in the last 10 years[7] suggested a positive impact of PSPs on patients' adherence to medication, satisfaction, or health-related quality of life. In addition, PSPs were found to ameliorate clinical outcomes or reduce the use of resources and costs. These suggested benefits should be qualified by the considerable heterogeneity amongst studies included in the meta-analysis and systematic review, by the (in general) lack of comparison with standard care, and by an absence of reporting of patient safety data.

None of the studies assessed a healthcare professional's perspective of the PSP. Reduced costs from PSPs have been demonstrated in the US health care system in a retrospective study of PSPs linked to biologic therapy.[8] The study found that disease-related costs and all-cause medical costs were significantly lower by 35% and 29.2% respectively for PSP versus non-PSP patients despite 12.2% higher drug costs.

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[6] Burudpakdee C, Khan ZM, Gala S, Nanavaty M, Kaura S. Impact of patient programmes on adherence and persistence in inflammatory and immunologic diseases: a meta-analysis. Patient Prefer Adherence. 2015;9:435–48

[7] Sacristan JA, Artime E, Diaz-Cerezo S et al. The Impact of Patient Support Programmes in Europe: A Systematic Literature Review Patient 2022 Jun 21. doi: 10.1007/s40271-022-00582-y. Online ahead of print

[8] Brixner D, Rubin DT, Mease P et al. Patient Support Program Increased Medication Adherence with Lower Total Health Care Costs Despite Increased Drug Spending. J Manag Care Spec Pharm. 2019;25(7):770-79

4. Key Principles and Governance Arrangements

To control PSPs a set of principles should be adopted that include the Royal Pharmaceutical Society's (RPS) Professional Standards for Homecare Services,[9] the National Homecare Medicines Committee's Good Practice Principles,[1] the ABPI's Guidance notes for patient safety and pharmacovigilance in patient support programmes[4] and follow the MHRA's expectations for the collection of safety data.[10] Some of the key principles and governance arrangements are listed below.

- The senior clinician requesting the scheme must complete an application form outlining the scheme, place in therapy of the drug and alternative options, potential benefits of the scheme, patient numbers, patient criteria, etc. prior to a scheme being agreed. They must also give assurances that the availability of the PSP will not influence prescribing decisions to any significant degree.
- All requests for PSPs must be approved by the system Drugs and Therapeutics Committee.
- PSPs will not be considered if the drug is about to come off patent and biosimilars are being launched.
- If the scheme is approved, the system Drugs and Therapeutics Committee will specify the patient cohort eligibility.
- PSPs must be signed by responsible persons agreed by the trust, e.g. chief pharmacist (or other senior pharmacist with budget responsibility), senior clinician, and trust chief nurse.
- There should be robust systems for provision of PSP service information to patients and carers.
- Patient consent and registration should be obtained using standardised and approved forms and patients must understand who will hold their personal data and how that data will be used.
- The MAH providing the PSP needs to share key information such as laboratory test results with patient consent with stakeholders including patient/carer, primary care provider and secondary/tertiary care provider where relevant.
- Patient safety is paramount and the MAH must provide robust arrangements for reporting of medicines incidents, adverse drug reactions and clinical incidents related to components of the PSP.
- Information governance should be followed as described in the NHMC PSP position statement at Appendix A and should also include a requirement for compliance with key standards, particularly the DCB0160 standard for any Health IT systems used in conjunction with the PSP. DCB0160 provides a set of requirements to promote and ensure the effective application of clinical risk management by those health organisations responsible for the deployment, use, and maintenance of Health IT

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[9] Royal Pharmaceutical Society. Handbook for Homecare Services in England. May 2014. www.rpharms.com

[10] MHRA Inspectorate. Patient Support Programmes. https://mhrainspectorate.blog.gov.uk/2020/05/07/patient-support-programmes/

Systems within the health and care environment.[11]
- Monitoring of the usage of the drug associated with the PSP versus other drugs used for the same condition will be done on a quarterly basis and will be reported to the system Drugs and Therapeutics Committee.
- An evidence base describing the impact and success of PSPs should be developed through collection of data on adherence, outcomes, patient activation, qualitative healthcare professional survey data, carbon savings, costs and benefits in comparison to standard care.
- The MAH should provide annual reports, including patient outcomes, and potential cost savings to the system through reduced patient contacts within the trust.

5. Conclusion

The NHS is looking to provide person centred care and promote self-management with care delivered wherever possible at, or closer to a patient's home, empowering people to live with and manage their long-term conditions. PSPs form part of the armamentarium to deliver this in a way that improves patient experience and health outcomes. PSPs can also improve treatment for people who may be affected by health inequalities, for example, because they live some distance from hospital and would find it difficult to attend training or seek help there. More widespread use of PSPs could address disparities in the care received by patients and help positively contribute to a greener NHS.

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[11] DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems. Applicability of DCB 0129 and DCB 0160 - NHS Digital

6. Appendix A: NHMC Position Statement: Manufacturer Funded Patient Support Programmes (PSPs) associated with a Homecare Service

Background
The National Homecare Medicines Committee (NHMC) is a subgroup of the Pharmaceutical Market Support Group (PMSG) and acts as the national focus for developing and improving administration and governance processes for medicine homecare services[1].

A homecare medicines service can be described as a service that delivers ongoing medicine supplies and, where necessary associated care, initiated by the hospital prescriber, direct to the patient's home[2]. This definition implies that core homecare medicines services provide product delivery and nurse administration and/or training elements. Any service that is provided over and above a core homecare medicines service is considered a Patient Support Programme (PSP).

Some pharmaceutical manufacturers include core homecare medicines services in their working definition of Patient Support Programmes which is a view that is not shared by the NHS. The Medicines and Healthcare products Regulatory Agency (MHRA) is currently looking at their working definition of homecare medicines services and Patient Support Programmes, so it is possible that in the future the pharmaceutical industry, MHRA and the NHS may align their working definitions for a more consistent approach.

The NHS should consider offering patients access to homecare medicines services and Patient Support Programmes that provide benefit by driving adherence and persistence and reduce waste only after careful risk assessment. The expectation is that such interventions lead to better clinical outcomes.

Introduction
Many pharmaceutical manufacturers (''manufacturer'') offer funded homecare medicines services to the NHS. Manufacturer funded services are typically 'dispense and deliver' services with/without product administration and/or administration training. Where this is offered by the manufacturer this means that the NHS is charged for the cost of the medicine and the delivery fee in a single 'bundled' price or package deal. Clinical responsibility for patient care is maintained by the clinical referring centre (referring hospital), and the Chief Pharmacist (or equivalent) is the Responsible Officer for the homecare medicines services.

Some manufacturers also offer additional enhanced services (motivational interviewing, disease scoring, test kits, phlebotomy, provision of medical devices and/or mobile Apps) to patients who are prescribed their medicines. These additional services are referred to by the NHS as Patient Support Programmes (PSPs).

The common aims of PSPs include but are not restricted to:

- Improve the patient experience
- Improve patient adherence and persistence with their treatment
- Support the uptake and understanding of their medicine
- Release NHS capacity
- Improve clinical outcome

PSP's may or may not be associated or linked to manufacturer funded homecare services. This position statement is only relevant to situations where the homecare service and PSP services are inter-linked.

Calls for evidence of the value of PSPs

There is evidence that some elements of PSPs, e.g. Patient Activation Measure (PAM)[3] provide benefits to patients however this is limited in the homecare setting because of the challenges in capturing appropriate consent from patients and accessing data relevant to patient health outcomes. NHMC welcomes the submission of publications or data on file to demonstrate the benefits of PSPs.

To be able to monitor and review their value it is essential for all PSPs to be designed with clear objectives, which must include measures for success and capture of any perceived benefits. These benefits should be aligned to the NHS Long Term Plan[4] and to NHS England's Improving Value in Specialised Services document[5]. Within each clinical referring centre the Director of Nursing (or equivalent) has responsibility for monitoring risks associated with any clinically-orientated Patient Support Programmes (PSPs)[6].

Well-designed PSPs will achieve one or more of the following outcomes:

- Improve patient safety
- Achieve better health outcomes
- Improve patients' experience of care
- Result in fewer episodes of unplanned or emergency care
- Provide financial benefit for the overall healthcare system
- Share outcome evidence with healthcare professionals

Examples of interventions to improve patient activation include

- Health coaching
- Self-management training Peer support
- Social prescribing

Good PSP’s are dependent on an understanding of the different patient cohorts with different conditions/needs where tailored interventions are applied in order to gain better health outcomes and benefits for the end-users. The current variation and complexity of PSPs offered to the NHS can be a challenge to measure and compare the effectiveness of these PSPs.

Agreeing a common set of measurable datasets may facilitate the benchmarking and monitoring of the effectiveness and outcomes of PSPs. Standardisation in PSP monitoring may give the NHS more confidence that the PSP will be of benefit. Homecare providers and manufacturers have expressed their willingness to collaborate with the NHS to shape the PSPs of the future.

Review of PSPs

NHMC is a medicines / pharmacy focused committee so support from clinical colleagues is essential when assessing or reviewing PSPs. It is also important that PSPs are not restricted to patients who are suitable for homecare medicines services. Patients who are not suitable for homecare medicines services may gain great benefit from the additional support offered by a well-designed PSP. A PSP that has no homecare elements or link to a homecare service is not within the remit of this paper, but the same design and governance principles could apply.

Governance of PSP’s

NHMC is aware of instances where patients have been permitted to self-register for PSPs via homecare providers without the knowledge or authorisation of their clinical referring centre (hospital). Once patients are registered for a homecare medicines service, any additional service offered to patients is likely to be considered by the patient to have been endorsed by their clinical referring centre. NHMC recommends that there should be oversight from the Director of Nursing (or equivalent) at each clinical referring centre before patients are offered a PSP. Directors of Nursing may delegate this responsibility to clinical teams as per individual hospital processes. Clinical referring centres must have a contract in place for any service that is offered to patients, this includes for PSPs. Pharmacy homecare teams should engage with clinical teams to ensure that the uptake of well-designed PSPs where benefits outweigh risks, is enabled to ensure that patients have the opportunity to benefit from the extra support available.

Contracting Models and Risks

There are a number of different contracting models for PSPs including:

- PSP provided by a stand-alone nursing agency
- PSP provided by a dedicated team of homecare provider employed nurses/staff
- PSP provided by a syndicated team of homecare provider employed nurses/staff
- PSP provided by a third party digital company

Manufacturers often consider their PSPs to be innovative. Innovation should be encouraged provided that the scheme is well-designed, and benefits outweigh risks.

Whilst PSPs provide benefits, NHMC recommends that each PSP is carefully considered, and steps are taken to identify and mitigate any risks. NHMC recommends that the following areas of risk are considered by each NHS organisation when deciding on access to a manufacturer funded PSP.

Clinical Governance

- PSP service provider registration
  - CQC registration in England or Care Inspectorate (CI) in Scotland
  - Care Inspectorate Wales (CIW)
  - Regulation and Quality Improvement Authority (RQIA) in Northern Ireland
  - Qualification and roles of staff providing the service
  - Disclosure and Barring Service checks (DBS)
  - Clinical risks with individual services, fragmentation of care pathways across interfaces (e.g. clinical data flow from multiple sources)
  - reduced patient interaction with clinical team, as patients' feedback directly to PSP provider, important clinical clues can be missed
  - patients prescribed 'off label' may not be able to access the PSP
  - Phlebotomy – transport of samples, availability and communication of results
  - Quality and standards of outsourced diagnostic, biochemistry or Therapeutic Drug Monitoring (TDM) testing

- Communication between the clinical teams and the PSP provider
- Communication between the clinical teams and the homecare provider
- Patient information leaflets
- Safeguarding
- Need for Honorary Contracts with NHS organisations/clinical referring centres

Operational Governance

- Qualification and appropriateness of staff grades providing the service
- Management of Complaints and Incidents
- Capacity planning
- Contingency Plans
- Inequality of service provision to certain patient cohorts or limited geographies
- Inequality of service if the PSP is only available to certain patient cohorts
  - licensed vs off-label use
  - only offered to registered homecare patients
- Risk of induced prescribing depending on the availability of PSP
- PSP Management of service cessation at short notice
- Management of service cessation at the end of the contract term
- Management of service switching to an alternative provider
- Administrative burden at clinics level (additional registration form, filing intervention forms) and at pharmacy level managing many contracts for different PSPs.

Information Governance

- General Data Protection Regulation (GDPR) compliance
- Data sharing arrangements
- Data Protection Impact Assessment (DPIA) completion
- Freedom of Information**:** An agreement should be in place with the provider on how to manage freedom of information requests.
- Use of manufacturer owned IT platforms, servers can be hosted outside EU at times.

Digital Products and Medical Devices Considerations

- Health Apps subject to DTAC and any other approval required for the devolved nations[7]
- Website content approval
- Diagnostic devices
- Remote monitoring of health app and diagnostic device data
- Devices and equipment to support patient self-administration of homecare medicines

Financial Governance

- NHS resistance to switching patients to a more cost-effective treatment which does not have a PSP
- The set-up and management costs of PSPs by the NHS should not be underestimated, e.g. SLA set up, legal review, ongoing performance management, including KPI review and managing complaints and incidents
- Commercial schemes attached with individual PSP adding risk to medicine pricing

Contractual Considerations

- Contractual relationship between the NHS and the provider of the PSP, any homecare provider if relevant and the funder of the PSP (e.g. subcontracting or tripartite arrangement)
- Is the PSP provider the same organisation as the homecare provider?
- Communication between homecare provider and PSP provider (if not the same organisation)
- Key Performance Indicators (KPI) should be available to the clinical referring centre
- Roles and responsibilities of all parties

Patient Support Programmes from the manufacturer perspective[8,9,10]

Patient safety is a priority and the pharmaceutical manufacturer must meet ethical, legal and regulatory obligations including pharmacovigilance requirements[8] as well as the ABPI Code of Practice and other requirements. PSPs may be a source of safety data (adverse events), therefore they generate additional obligations and regulatory authority expectations which may not be fully understood by other stakeholders.

Manufacturers may perceive PSPs as driving patient concordance/adherence[9] to medicines and improve patient outcomes.[10] Manufacturers may also perceive PSPs as bringing commercial and reputational benefits to their company as well as benefits to the patient and healthcare system.

Collaboration with NHS stakeholders is encouraged so that the needs of patients can be met through good programme design with clear goals, KPIs and outcome measures.

Recommendations

NHMC recommends that manufacturers wishing to design Patient Support Programmes should engage early with NHS clinicians and other stakeholders to ensure the PSP is designed to include the collection of an agreed minimum dataset and that the PSP can be offered to all patients prescribed the medicine, irrespective of the route of supply of the medicine. Feedback from the homecare providers and / or other PSP delivery partners based on their operational experience should also be sought to shape the final design of PSP.

It is essential that the PSP is designed from the outset with clear aims and Key Performance Indicators (KPIs) which align with NHS values. Clear measurable outcomes for each of the identified specific patient cohorts who may benefit from the various optional interventions must be determined and made available to the NHS both at PSP set up and periodically reviewed by all stakeholders during the lifetime of the PSP. Uptake and outcome data must be shared with the NHS and where relevant with NHMC.

For PSP's associated with a Homecare service, a set of standards could be defined by a NHMC working group and included into existing RPS guidelines.

As a starting point, the NHMC has proposed 4 core common objectives to be measured to help understand the success of a PSP:

1. Percentage of hospitals opting into the use of the PSP
2. Out of these, the percentage of patients who enrolled in the PSP
3. Of these patients, the number of touch-points the patients used against the total number of touch-points available
4. The length of time the patient remained in the PSP / Percentage of patients who completed the full duration of the PSP if a limited duration
5. A measure of adherence/persistence with the medicine concerned (where applicable)

When considering a PSP, the Director of Nursing (or equivalent) at each NHS organisation must satisfy themselves that the risks highlighted above have been reviewed, documented and mitigated, and appropriate governance is in place before patients are referred to the PSP.

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