CHARTERED SOCIETY OF PHYSIOTHERAPY

14 Bedford Row, London WC1R 4ED
Tel +44 (0)20 7306 6666
Web www.csp.org.uk

Information paper

Therapeutic injection-therapy in physiotherapy practice.

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Definitions and Scope

Therapeutic injection therapy has been accepted as within the scope of physiotherapy practice since 1997. ‘Injection therapy’ in the context of physiotherapy practice is the use of selected licensed Prescription Only Medicines (POMs) and other products which are administered by injection to the intra-, and extra- articular soft tissues and joint spaces of the peripheral (appendicular) and/or spinal (axial) skeleton. Injection-therapy also includes the aspiration of joint spaces.

‘Injection therapy’ does not include

- performance of General and/or Regional Anaesthesia such as nerve blocks for the management of chronic pain
- the cosmetic use of injectable medicines and/or products and devices.
- Subcutaneous, intra-muscular and/or other parenteral administration of medicines and/products
- Vaccination
- Medicines administered via intravenous, catheter or syringe driver routes

Physiotherapists working in the neurological specialities use Botulinum toxin in injection-therapy for the physiotherapeutic treatment of spasticity and dystonia, and chronic headache including migraine.

Physiotherapists working in the musculoskeletal specialties use corticosteroid with or without local anaesthetic, with or without inert substances as a vehicle for administration, to treat a range of joint and soft-tissue inflammatory and degenerative disorders.

Physiotherapists may use their initial training in injection therapy as a stepping-stone to develop additional advanced practice skills, such as

- performing peripheral nerve blocks, and performing spinal injections.
- IV, catheter and syringe driver administration of medicines

These skills require additional training which is outside the scope of this document.

Members must check their PLI indemnity position before undertaking any advanced practice activity requiring injection skills, as the activity many not be covered by the CSP PLI scheme.

Knowledge and Skills

It is essential to separate the skill of delivering the intervention of 'injection therapy' from the professional activity of using medicines and/or devices as part of professional practice.

Injection Therapy Skills

Injection therapy is not subject to statutory regulation. A physiotherapist does not have to be an independent prescriber to perform therapeutic injection therapy. You must undertake an initial training programme in injection therapy that meets CSP requirements. Please refer to PD071.

Medicines Use

All physiotherapists may administer medicines by injection-therapy on the delegated instruction of an appropriate prescriber, in accordance with the terms of the prescription (aka PSD)

Some physiotherapists will be able to supply and administer medicines by injection-therapy in accordance with a Patient Group Direction (PGD). There are legal restrictions as to what medicines can be included in a PGD and how they can be administered e.g. mixing of medicines cannot occur.

Physiotherapists who are annotated with the HCPC as an independent prescriber may prescribe, supply and administer the medicines used in therapeutic injection therapy.

Supplementary prescribers can prescribe and administer the medicines used in therapeutic injection therapy, provided there is a written clinical management plan (CMP) signed by a doctor in place before the prescribing occurs.

The HCPC is clear that registrants must follow the law relevant to their practice, including keeping within the medicines entitlements for their profession at all times.

Products used in injection-therapy

The products used in therapeutic injection therapy may include

- licensed medicines (listed within the British National Formulary)
- medical devices (certified with a CE mark)
- some blood products (i.e. Plasma Rich Proteins).

At the current time the CSP does not consider the use of the following products/uses to be within the scope of therapeutic injection therapy:

- Products derived from stem cells or non-blood substrates e.g. Lipogems™ from lipid cells
- Medicines and devices used for the purpose of wholly cosmetic effect such as wrinkle reducing injections and dermal fillers and or facials.
- Medicines used for regional and/or general anaesthesia

Devices

Some products used in the management of degenerative diseases have a ‘physical’ mode of action as opposed to a ‘medicinal’ action. Such products may include lubricants such as ‘Ostenil’.

As such products are not classified as ‘medicines’ under medicines legislation, a written prescription is not required for their supply. However, manufacturer guidelines often stipulate that such products can only be supplied to registered health professionals and/or used under the direction of a doctor or registered health professional.

Whilst a legal written prescription is not required, good practice dictates that appropriate written policies and records are in place when such products are used.

Prolotherapy

This involves the injection of naturally irritant substances into joint spaces, ligaments and/or tendons, with a view to provoke inflammation to seek to promote healing.

Substances such as Lidocaine, Procaine, Dextrose (sugar) and/or saline may be used.

Where the substances used are classed as ‘medicines’, then they must only be prescribed, supplied and administered using an appropriate medicines framework.

Where the products used are not medicines, good practice dictates that appropriate written policies and records are in place when such products are used.

Members using prolotherapy as part of physiotherapy injection therapy practice must also consider the reasonable evidence base for the technique, and in particular if there is any specific guidance, such as NICE Guidance, that advises that the techniques are not recommended.

Training in Injection Therapy

Injection therapy is not subject to statutory regulation.

Since April 2011, the CSP has required that members who wish to use therapeutic injection therapy as part of their practice can demonstrate that their education and training in injection therapy meets CSP expectations. Members are required to complete 150 hours of training including supervised practice, and formal assessment of capabilities.

Validated courses provided by UK HEI institutions, as well as those provided by recognised professional organisations such as SOMM and OMS meet these standards.

It is members' own responsibility to be assured that they can demonstrate their education and training meets CSP expectations should they be asked to provide evidence of their initial training.

Further information about our expectations of training is in PD071.

Our training expectations only apply to therapeutic 'injection-therapy' and do not apply to other parenteral interventions. Members should seek the advise of their employer for details on the training required to establish competence in these skills and undertake these interventions safely.

Governance

Members practising injection therapy in all settings must ensure there is appropriate governance in place to ensure they can deliver injection therapy safely, effectively and review practice is required.

In NHS settings, governance processes may be controlled by the Trust/Board. In independent private practice, members may need to establish these processes themselves.

There should be governance structures in place for

1. Information provision; consent forms, Patient Information Leaflets, advice sheets and exercise plans.
2. Care pathways and clinical decision-making
3. Supervision and Continuing Professional Development.
4. Infection Prevention and Control
5. Medicines administration frameworks
6. Injection therapy policy
7. Injection therapy procedure
8. Record keeping including patient follow-up
9. Communication
10. Audit and quality improvement
11. Incident reporting
12. Adverse reaction reporting

PLI Indemnity

All registered physiotherapists must have appropriate insurance in place for their work. This may be provided by an employer, as benefit of a professional body membership, or purchased from an insurance provider.

Therapeutic Injection therapy used as part of physiotherapy practice is covered by the CSP PLI scheme for members, subject to the policy terms and conditions.

Members are reminded that the following activities are not covered by the CSP PLI scheme:

- all injectable products such as medicines and fillers, used for cosmetic purposes,
- regional and general anaesthesia
- spinal injection therapy (from 1st July 2021)

Injection Therapy in independent private practice

Regulation

The Care Quality Commission (CQC) regulates health and social care provision in England, which regulates all NHS providers of services. Scotland, Wales and Northern Ireland have their own statutory health inspectorates for NHS services and independent practice.

Individual HCPC registered physiotherapists in independent private practice are exempt from CQC registration, their clinic may require CQC registration if they engage specified other health professional groups to deliver injection therapy services.

Medicines Use

Independent clinics which are registered with CQC are able to create their own Patient Group Directions (PGDs) for use with their private patients, subject to certain conditions being met.

Independent clinics that provide services to NHS patients under formal written NHS contracts are also able to use NHS PGDs to treat the NHS patients treated under the contract.

Other independent private practitioners are exempt from CQC registration and so do not meet legal requirements for PGD creation. Individual private practitioners can supply and administer injection therapy in accordance with a written prescription from a doctor or other prescriber, or they can privately prescribe the medicines required if they are annotated with the HCPC as a supplementary/independent prescriber. If you prescribe as an independent prescriber in private practice the patient is liable for the full costs of the medicines and associated costs.

If you are a private practice physiotherapist, you cannot ask a GP to prescribe medicines for your private patients for you to administer in your private practice. This is because a GP is a doctor who is contracted to provide primary medical services on the National Health Service to patients who sit within a defined **NHS** catchment population. GP's prescribe NHS medicines that will be dispensed at NHS expense.

Prescribing medicines at NHS expense to be used in private practice may be theft and/or fraudulent use of NHS resources which may be subject to regulatory action if reported. Some GP's may be unwilling to write private prescriptions for patients who are on their NHS lists, for medicines and services that are available on the NHS.

Accessing supplies of medicines for independant practice use

If you run a private practice you must consider how you will procure the medicines you need in order to offer injection therapy services. This may influence your business decision as to whether it is feasible for you to offer injection therapy services in private practice.

If you are an independent prescriber, you will be able to prescribe the medicines your patient needs. They can then obtain the medicines from a pharmacy and return for their injection.

If you are a supplementary prescriber, you must consider if you have a working partnership with a private doctor such that you are able to use a CMP to prescribe your medicines. This may be possible in larger multidisciplinary clinics, but may not be possible in small or single handed clinics.

PGDs can only be used in certain types of private clinic, e.g. those which are CQC registered or have a formal agreement to provide NHS services to patient in a private setting. If you work in a private setting where you cannot use a PGD, and you are not an independent prescriber, you must use a PSD.

If you cannot use any of the mechanisms above, you can only use a PSD. This means you will need to ask a private doctor to prescribe the medicines for your patients. The patient can then obtain the medicines from a pharmacy and return for their injection. They may agree to do this on your remote recommendation, but they may ask to see the patient, or decline to prescribe for your patient.

If you run a private practice you may be able to order some injection therapy supplies in bulk and store them on your premises:

- There are no legal restrictions on obtaining stocks of GSL medicines[1].
- For P medicines, you are allowed to receive stocks of any which are needed for the purpose of administration in the course of your business as a physiotherapist[2].
- You **cannot** order or receive stocks of POM[3] medicines under any circumstances. This means they must be prescribed as needed and then obtained via a dispensing pharmacist.

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[1] Section 249 Human Medicines Regulations 2012
[2] Section 250 Human Medicines Regulations 2012
[3] Section 249, Schedule 22 of Human Medicines Regulations 2012