

# Therapeutic Lumbar Puncture

## The Future of Neurological Innovation

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# The frontier of medicine

**It is an exciting time for science.** Advancements in our understanding of the building blocks of disease are enabling the development of better treatments, which are now able to target specific areas of the body or the underlying genetic causes of conditions. This new generation of medicines offers hope to patients with conditions for which there may have been no effective treatments before.<sup>1</sup>

As the UK Government has recognised, the life sciences sector has the potential to transform our nation's health by working with the NHS to enable these innovations to be adopted.<sup>2</sup> This means partnership working across the access pathway: from the clinical trials that are needed to demonstrate efficacy, through the evaluation processes that determine if new medicines should be made available to patients, and finally to ensuring that services have capacity to deliver them.

Some types of new treatments require more intensive support, particularly where they involve new or uncommon procedures to deliver them to patients. Lumbar puncture is one such example. Whether for cancer or rare genetic conditions, a lumbar puncture can be used to administer medicine directly into the spine and the nervous system with a needle.<sup>3</sup>

**Lumbar punctures can enable patients to receive potentially life-changing medicines, such as for neurological conditions.** Demand for lumbar puncture is likely to rise as more intrathecally administered medicines are developed and approved for use. The NHS must keep up with the pace of innovation by ensuring that services have sufficient capacity to deliver these medicines. Without greater ambition and investment in services, patients will miss out.



A series of seven green circles of varying sizes are arranged in a diagonal line from the bottom-left towards the top-right. In the background, there is a faint, light blue illustration of a human brain and spine, with the brain showing gyri and sulci, and the spine showing vertebrae.

## About this report

**Biogen has undertaken this research and report to help expand the evidence base on how lumbar puncture is used to administer medicines in England and enhance understanding of the capacity challenges that services are experiencing.** At present, there is limited up-to-date information in the public domain, including how many are performed each year, which settings perform the procedure routinely, and which staff are involved.

In producing this report, Biogen spoke to healthcare professionals, patient organisations and policymakers across the UK in 2024 to learn how lumbar punctures are performed in clinical practice to administer medicines in the NHS. Contributors include consultant neurologists and a clinical nurse specialist, based in several NHS settings across the UK; the patient organisation SMA UK; and the Highly Specialised Commissioning Team in NHS England. These insights have been reflected throughout this report, including in the recommendations.

This report focuses specifically on lumbar punctures performed to administer medicines, rather than performed to make a diagnosis, as significantly more is known about the diagnostic procedure. Although some insights may also apply to diagnosis, this report focuses on the specific challenges and opportunities in administering medicines via lumbar puncture. This report also largely focuses on lumbar puncture delivery in England; however, the recommendations may also apply to services across the devolved nations.

# Lumbar puncture 101

## What is a lumbar puncture?

A **lumbar puncture is a precise medical procedure, also commonly known as a *spinal tap***. A lumbar puncture is performed by inserting a thin needle between the bones of the lower spine to reach the cerebrospinal fluid (CSF), a watery fluid which surrounds the brain and spinal cord.<sup>3</sup>

A lumbar puncture is usually performed in a hospital or other outpatient setting while under local anaesthesia. The procedure itself usually takes around 30 minutes, with an additional 1 to 2 hours for rest and monitoring afterwards, but this can vary based on the complexity of the procedure. It is considered to have a well-established safety profile and serious side effects are uncommon.<sup>3,4</sup>

## What are the different types of lumbar puncture?

There are two different types of lumbar puncture for separate purposes:



### Therapeutic lumbar puncture

As previously outlined, a lumbar puncture can be used to administer certain types of innovative medicines. A lumbar puncture allows the medicine to be directly injected into the cerebrospinal fluid, specifically targeting the central nervous system (CNS). Administering medicines in this way into the body is also known as *intrathecal administration*. Where patients have more complex medical needs, a therapeutic lumbar puncture is sometimes combined with imaging techniques such as ultrasound or interventional radiology (IR).



### Diagnostic lumbar puncture

A lumbar puncture can also be a powerful and precise diagnostic tool. A diagnostic lumbar puncture either collects a sample or measures the pressure of the CSF. Lumbar puncture is used in the diagnosis of a wide range of conditions, including Alzheimer's disease, bleeding around the brain, certain cancers involving the brain or spinal cord, and neurological conditions such as multiple sclerosis (MS).<sup>5,6</sup> Whilst the technique is the same for both types of lumbar puncture, the day-to-day delivery varies and they are regarded as different procedures.

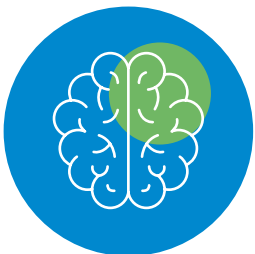
## Which conditions can be treated with medicines administered via lumbar puncture?

**There are a range of conditions which can be treated with medicines administered via lumbar puncture.**

In the UK, the most common usage of therapeutic lumbar puncture is to administer chemotherapy medicines. For certain cancers, such as some leukaemias or lymphomas, the cancer cells can pass directly into the cerebrospinal fluid.<sup>7</sup> Chemotherapy can therefore be administered via lumbar puncture to specifically target the cerebrospinal fluid if the cancer has spread there or is likely to; in contrast, chemotherapy given into a vein or taken orally cannot easily reach this area, meaning lumbar puncture is vital in improving the effectiveness of the medicine.<sup>8</sup>

Medicines known as antisense oligonucleotides (ASOs) can be administered via lumbar puncture. Whereas chemotherapy targets cancer cells in a particular part of the body, ASOs are designed to target specific elements of a person's genes with high precision.<sup>9</sup> **These medicines have the potential to slow down or halt progression altogether for some rare genetic conditions, and can even be tailored for target groups or individuals in the patient population.**<sup>10</sup>

Although ASOs have revolutionary potential, delivering these medicines across the body is challenging and research is still in its relative infancy.<sup>11</sup> While other methods of administration do exist, giving the medicine locally – in the specific area of the body the ASO is targeting – may be the most effective and safest method.

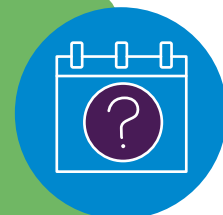


For neurological and spinal cord-related conditions, this means ASOs may need to be delivered by therapeutic lumbar puncture. Some rare and complex neurological conditions can be treated with these precise medicines today,<sup>9</sup> whilst research is underway to explore how ASOs could treat both Huntington's and Parkinson's disease.<sup>12,13,14</sup>

## How many therapeutic lumbar punctures are performed each year?

**The only publicly available data suggests that there are around 15,000 therapeutic lumbar punctures performed each year in England.**<sup>15</sup>

However, this figure dates back to 2018; it is therefore reasonable to expect this figure to have increased since then.



# Opportunities to improve and widen lumbar puncture provision

**In speaking to healthcare professionals and policymakers involved with delivering therapeutic lumbar puncture in the NHS, we learnt that there are several challenges limiting the capacity of the system to deliver medicines to patients.** Given the number of medicines that may be launched over the coming years, there is a need for action to address these challenges, enabling more patients to benefit now and ensuring the system is better equipped to meet growing demand in the future. As a first step towards this, Biogen has identified several opportunities through which care provision could be improved and enhanced.

## Greater guidance on what ‘good’ looks like

**The overarching challenge in enabling services to administer medicines via lumbar puncture is a lack of national guidance in England.** There are no central guidelines for what ‘good’ therapeutic lumbar puncture delivery looks like in the NHS. When a hospital or other setting begins administering a medicine to patients via lumbar puncture, they develop their own guidance or model of care, usually through standard operating procedures (SOPs). This creates significant variation across the country in day-to-day delivery and the care that patients experience.

With responsibility falling on individual services, NHS England (NHSE) does not have a clear or holistic picture of how medicines are being administered via lumbar puncture. Lumbar puncture only appears on NHSE’s radar in relation to specific conditions or medicines, rather than as a cross-cutting issue or as its own service. NHSE would therefore not make a proactive assessment on the state of lumbar puncture delivery beyond individual medicines; NHSE relies on any issues being raised directly with them by services, healthcare professionals or patients.

When an innovative medicine which requires administration via lumbar puncture is approved, NHSE does not see its role as directive in terms of specifying what ‘good’ therapeutic lumbar puncture looks like. It is the responsibility of individual services to approach NHSE with their own model and demonstrate to commissioners that they can safely and effectively begin to administer medicines to patients. Commissioners may ask about the SOPs the Trust has in place and take a view on whether these are appropriate and sufficient, but there is no central guidance. As certain specialised services in England are delegated to Integrated Care Systems (ICSs), these commissioning decisions will become less centralised over time and therefore potentially subject to greater variation.

As we will explore in the following pages, **this lack of national guidance from NHSE ripples out to create further challenges.** Clarity on how medicines should be administered effectively and safely via lumbar puncture could address the challenges outlined in this report. We heard that high-level guidance from NHSE would be welcomed by both healthcare professionals and services; patients and their families could also benefit by providing reassurance that the care they receive is of the requisite standard.

Such guidance could set out the considerations that services should make in beginning to administer a new medicine via lumbar puncture – as we will come to explore, this could include hospital delivery models, staffing capacity, and training opportunities. This would differ from existing service specifications, which are condition-specific. We know that NHSE wishes to maintain the autonomy of services in deciding how to best meet the needs of their local populations, and therefore is hesitant to issue prescriptive guidelines where they are not needed. Publishing a list of considerations for services could therefore strike a good balance.

## Recommendation

### **NHS England should publish high-level national guidance on therapeutic lumbar puncture.**

This guidance should cover the key considerations that services should take into account when beginning to offer new medicines via lumbar puncture, with a focus on how to deliver the best care for patients. This guidance should be published in the public domain in the form of a short document, setting out what good therapeutic lumbar puncture looks like, above the level of specific conditions or medicines.



## Making space for new medicines

Medicines which require lumbar puncture are often administered within existing oncology units in a hospital setting, which are well-established to provide chemotherapy through this route. This means that patients with complex, non-cancer conditions may be admitted into an oncology unit to receive their treatment. This has some benefits for patients, as oncology units typically have full-time nurse supervision, and are equipped with both recovery areas and designated areas for families.

### Case study: Treatment in an oncology day unit

In one hospital in the North of England, patients with neurological conditions receiving medicine via lumbar puncture are admitted to the hospital's oncology day unit at the beginning of the day before scheduled chemotherapy appointments. These patients are then able to recover in the unit with their families while cancer patients arrive for their chemotherapy treatment.



### **However, delivering lumbar punctures for non-cancer medicines in oncology units can also create challenges.**

These settings are rarely designed for patients with differing complex needs – for example, the units are not typically fitted with hoists to move non-ambulant patients or pressure-relief mattresses, which may be needed for patients with neurological conditions. The needs of people living with long-term complex conditions are different to those receiving shorter-term chemotherapy, which the current model does not account for. In these settings which routinely administer chemotherapy via lumbar puncture, there can be hesitancy amongst oncology staff to admit non-cancer patients onto their unit for treatment given the complexity of their needs.

Even in settings with well-established and well-equipped chemotherapy delivery, beginning to administer a new non-cancer medicine therefore brings significant challenges. For the NHS, the unit must find the time, the space and the staff to treat these patients without disrupting planned chemotherapy. With capacity and funding tight across the health system, and rising demand for cancer treatment, making the space to administer new medicines is challenging.

**For patients, especially those with long-term complex neurological conditions, lumbar puncture becomes a routine part of their lives.** It is therefore important that their care is designed to accommodate their specific needs, which may be different to people undergoing treatment for cancer. Appointments should be scheduled far enough in advance to fit around existing commitments and be kept to time where possible, especially for people who are accompanied by paid carers or assistants who may have to pay out of their own pocket for overtime caused by NHS delays.

With the next generation of medicines in the pipeline which will require administration via lumbar puncture, the NHS must proactively prepare for their arrival to ensure capacity can keep up with the pace of innovation.<sup>12,13,14</sup> NHSE should make an assessment of the anticipated capacity implications for settings and ensure support is in place, so patients do not face unnecessary delays once a new medicine is approved. We know similar horizon scanning is already being carried out by NHSE for diagnostic lumbar puncture to prepare for the arrival of treatments for Alzheimer's disease.<sup>16</sup> A similar model should be applied for therapeutic lumbar puncture to support patient access over the coming years.

## Recommendation

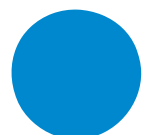
**NHS England should conduct horizon scanning to prepare for the arrival of new medicines which will require administration via lumbar puncture.** To ensure the NHS can keep up with the pace of innovation, horizon scanning should focus on the capacity implications of administering a new medicine, as well as the infrastructure and resources required to deliver the best possible care for patients with complex conditions. NHSE could look to adopt a similar model to their ongoing assessment of diagnostic lumbar puncture for Alzheimer's disease.



## Sharing best practice to reduce variation

**Access to therapeutic lumbar puncture varies significantly across the UK.** Many patients must travel long distances or may not be able to receive their preferred treatment. The Getting It Right First Time (GIRFT) national specialty report for neurology, published in 2021, agrees that geographical variation in access to lumbar puncture exists across England and recommends that patients should “*reasonably expect to be able to have an outpatient lumbar puncture done at their local hospital*”.<sup>17</sup>

Whilst this recommendation may be primarily aimed at diagnostic rather than therapeutic lumbar puncture, GIRFT does recommend that ICSs should collaborate across boundaries to treat patients via lumbar puncture, as not every ICS has the requisite capacity or resources.<sup>17</sup> Patients will always need to travel some distance to be treated via lumbar puncture because it is a specialist procedure. Nonetheless, more can be done to reduce the postcode lottery and ensure that all patients can access high-quality care, wherever they live.



## Patient case study: “My lumbar puncture experience has been very different across NHS hospitals”



**One woman living with a neurological condition shared her story with us.** She has received medicine via lumbar puncture across two different settings in England: a large hospital over two hours away from where she lives providing specialist care, and her local hospital which has not been set up for complex cases like hers. She describes how her experience of treatment has been “very different” across these settings.

After a year travelling to the specialist hospital, she transferred to her local hospital two years ago where she says the procedure is more painful and “distressing”. She arrives as requested at 8.30am for treatment, but is generally not seen until 4pm when there is a break between emergency admissions. There is no access to a pressure-relief mattress to give her a break from her wheelchair, or suitable toilet facilities. She is acutely aware of how busy the healthcare professionals delivering the procedure are, which leads her to feel “rushed through and not welcome”. On one occasion, she describes how she felt the medicine was administered too quickly, which caused more pain during the lumbar puncture itself and in the days afterwards, affecting her ability to return to work.

In contrast, her experience at the large hospital was “far more positive”. Her care was overseen by a specialist nurse; she had a fixed appointment time and regularly saw the same practitioner who learnt the complexity of administering treatment. She describes the lumbar puncture as less painful, both during the procedure and over the following days. She would prefer to transfer back, but she cannot afford the significant costs of overnight accommodation and hiring a hoist for a local hotel. If she had not had this more positive care experience, **she fears she would be ceasing treatment altogether.**

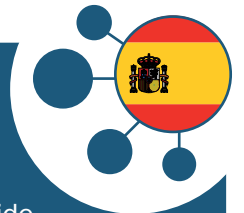
**From patient testimony, we know that there are settings delivering high-quality care for patients with complex needs which can serve as a blueprint for others.** The sharing of best practice can help to reduce unwarranted variation. However, at present the delivery of therapeutic lumbar puncture in different parts of the country is siloed, because settings operate under their own individual processes and protocols.

**NHSE therefore has a vital role to play in connecting these pockets of best practice.** Services should be encouraged to share learnings and healthcare professionals should be emboldened to share their expertise on a national scale – for example, how services are able to schedule treatment for non-cancer patients within oncology units, or distribution of training resources. The patient voice should be reflected in this best practice sharing, by investigating where patient satisfaction is highest and taking learnings from these settings. Seeking feedback from patients and their families or carers on whether services accommodated their more complex physical needs is an important aspect of this.

The benefits of this best practice sharing are two-fold: services already administering particular medicines via lumbar puncture can learn from each other to continually improve their methods and the patient experience; furthermore, new services can be encouraged to begin administering medicines by having access to existing models of care they can replicate. Rather than each service needing to reinvent the wheel, a collaborative approach can lead to greater consistency, which ultimately benefits both patients and the NHS.

We also heard that clinical trials offer valuable learnings to support services in beginning to administer newly approved medicines via lumbar puncture. Examples of these learnings include where efficiencies can be found – not just in the performance of lumbar puncture itself, but also in wrap-around care – and aspects of the patient experience which the NHS should anticipate. However, it is important to recognise that translating lessons from clinical trials into clinical practice is not a direct process. Clinical trials are typically better staffed and resourced in comparison with day-to-day NHS services, meaning that learnings must be contextualised and adapted.

### Case study: Best practice sharing in Spain



To inform this report, Biogen also sought insights into therapeutic lumbar puncture outside of the UK. In Spain, we heard that there is a strong culture of best practice sharing. Services and the healthcare professionals working with them have proactively established open channels across the country to share lessons from administering medicines via lumbar puncture. Rather than operating in siloes, services in Spain have formed a strong network of communication. This approach is helping to reduce geographical variation in the quality of care patients receive; A similar model could be adopted in England, led by NHSE, as a simple and low-cost intervention.

### Recommendation

**NHS England should facilitate the sharing of best practice between services and the healthcare professionals who work within them to reduce variation across the country.**

Sharing best practice examples of therapeutic lumbar puncture delivery can limit siloed working and provide a tailorable model for services which are not already offering the procedure. These examples should reflect the patient experience as well as clinical expertise.



## Supporting staff to deliver high quality care

**We heard that therapeutic lumbar punctures are delivered by a wide variety of healthcare professionals across England.** The procedure can be performed or supported by consultant neurologists, anaesthetists, surgeons, nurses and physician associates (PAs). The decision on who can administer medicines via lumbar puncture is taken by individual services, rather than guided by NHSE.

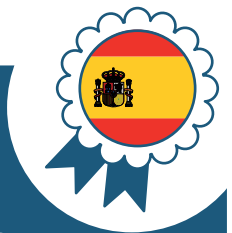
Capacity of staff is reported to be a challenge in the ability of some services to begin administering new medicines via lumbar puncture. We heard that workforce shortages across the NHS present a barrier to wider rollout; for example, the Royal College of Radiologists reports that the IR workforce has an 8% vacancy rate, which may affect patient access to more complex lumbar puncture procedures where imaging technology is required.<sup>18</sup> Services may be hesitant to offer a new medicine if their staff feel their current workloads are unmanageable, and an overburdened workforce has a direct impact on patient experience.

Training was also raised as an area for improvement. We heard that training to perform a therapeutic lumbar puncture is not standardised, meaning different types of healthcare professionals receive different levels of training. It was suggested that there is less expertise in lumbar puncture in the NHS compared to twenty years ago as a result, despite many new medicines arriving in this time. The lack of clear national guidance on training is creating hesitancy due to perceived risk, meaning that patients are missing out.

### Case study: Centres of excellence in Spain

We heard that Spanish healthcare professionals receive training at centres of excellence to administer medicines via lumbar puncture. Healthcare professionals rotate to these centres for at least a day to learn how to perform the procedure and observe what high quality patient care looks like. This training forms part of what is known as a preceptorship – a period of transition where newly registered practitioners learn new medical skills to build confidence and competence.

For neurological conditions treated via lumbar puncture, patients are also treated in oncology units, similar to England, and the expertise of oncology staff is regarded as invaluable in the training process. Training is aided by a better-staffed neurology workforce in Spain, totalling 6.6 neurologists per 100,000 people, in comparison to just 1.3 in the UK.<sup>19</sup>



**These workforce challenges could be addressed by clearer national guidance.** The GIRFT national specialty report for neurology highlights the value of training advanced practitioners, including specialist nurses and physician associates, to perform lumbar punctures.<sup>17</sup> However, the report places the responsibility on individual services to provide these training opportunities. We heard that advice issued by NHSE, or other bodies such as the Royal Colleges, on who can perform a therapeutic lumbar puncture and the level of training they should receive would be welcomed.

This guidance could be developed by collating and condensing existing training resources developed by services, as well as taking learnings from how training is delivered successfully beyond England, such as in Spain. The intention of this advice would not be to change how services already successfully train their staff, but to support additional services to train staff and provide a model to alleviate capacity concerns. Therapeutic lumbar puncture is a specialist procedure, requiring a high level of training; greater clarity around these staffing issues can incentivise healthcare professionals to enhance their skills and train in an exciting area of medicine.

## Recommendation

**NHS England or relevant Royal Colleges should issue advice on managing staff capacity and standardised training requirements to perform a therapeutic lumbar puncture.** This guidance should collate and condense existing resources where services already have a strong model in place, and draw on international best practice, to support additional services to begin to administer medicines and deliver the best possible care for patients.



# Conclusion

This report has explored how medicines are administered via lumbar puncture across England today. Lumbar puncture is used in the treatment of many varied conditions and sits within many care pathways; this means that it is not assessed at a holistic level in the NHS, beyond specific conditions or medicines. This report has explored the challenges this creates, primarily a lack of clear guidance on: what good therapeutic lumbar puncture looks like for patients and the health system; how services can find capacity to administer a new medicine; where to find examples of best practice; and who can perform the procedure and what training they need.

However, there are also clear opportunities to address these challenges and ensure that any patient who would benefit from medicine via lumbar puncture is offered it. **Greater guidance at the national level can both support the NHS to treat patients via lumbar puncture today and prepare the system for the arrival of the next generation of precision medicines on the horizon.** Although our report has focused on England specifically, the recommendations may apply to service improvement across the whole of the UK.

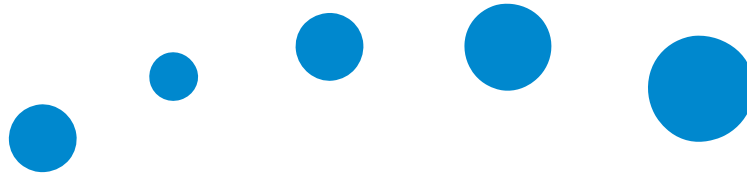
We recognise that NHSE wants to empower local decision-making and allow services to develop their own models of care. Where services are already performing therapeutic lumbar puncture successfully, this is the right approach; however, there is a risk that further patients could miss out on access to innovative medicines without greater direction from the top. Biogen therefore sees an opportunity to create a positive and sustainable cycle:

**Greater national guidance from NHSE to help services to administer medicines via lumbar puncture,** leading to wider patient access and higher quality of care



**Wider patient access to medicines via lumbar puncture and higher quality of care,** leading to a reduced need for national guidance from NHSE as services develop specialism

**The NHS is at the frontier of granting access to this new generation of medicines but must keep up with the pace of innovation.** High-quality lumbar punctures are vital in enabling patients to receive potentially life-changing medicines. Through collaboration between the NHS, healthcare professionals, patient organisations and industry, we can work together to ensure that this potential becomes a reality.



If you have any questions or would like to discuss any of the issues raised in this report, please contact Jessica March, External Affairs Lead for Rare Disease at Biogen UK & Ireland, at [jessica.march@biogen.com](mailto:jessica.march@biogen.com).

## About Biogen

Founded in 1978, Biogen is a leading global biotechnology company that has pioneered multiple breakthrough innovations for people living with serious neurological diseases as well as related therapeutic adjacencies. Biogen has a portfolio of medicines and potential therapies across neurology, neuropsychiatry, specialised immunology and rare diseases and remains acutely focused on its purpose of serving humanity through science while advancing a healthier, more sustainable and equitable world.

To learn more, please visit [www.biogen.uk.com](http://www.biogen.uk.com).

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