Department of Health announce new accelerated access scheme to breakthrough drugs

3 November 2017

On Friday morning, the Department of Health announced a new, fast-track route into the NHS for “breakthrough” medicines and technologies.

This means that, from April 2018, selected ‘breakthrough’ treatments, with the greatest potential to change lives, could be available up to four years earlier.

The key announcements are:

- The creation of an Accelerated Access Pathway (AAP) from April 2018.
- The establishment of an Accelerated Access Collaborative (AAC) before the end of 2017 to oversee the AAP.
- The introduction of additional commercial negotiating capacity within NHS England, including responsibility for Patient Access Schemes.

These developments could be significant for people living with muscle-wasting conditions as it could remove some of the barriers that currently delay access.

Commenting on the news in a Letter to the Editor in the Daily Telegraph, CEO of Muscular Dystrophy UK, Robert Meadowcroft said:

“Plans for faster access to new treatments on the NHS (report November 3) are welcome, but the scope of the programme is limited. Only five drugs a year will benefit, and the focus will be on what have been tagged ‘breakthrough’ treatments, with no detail yet on what that means.

We are seeing a revolution in precision medicines, offering custom therapies for specific variants of all sorts of conditions. However, it is unclear if these will be eligible for the new scheme. They need to be if the NHS and its patients are to benefit from the latest treatment.

These niche treatments should benefit everyone, including those with rare diseases. We saw lengthy delays for the first genetic treatment for Duchenne muscular dystrophy, meaning children in Britain got access years after children in Europe, and we need to ensure that future treatments don’t face a similar fate.”
Some key areas from the Department of Health report that we will be looking into further are:

- There is no further information on what drugs will be considered for breakthrough status or who will make that decision which is a concern. We will be looking to get more clarity around this.

- The Department of Health states that they “anticipate that ~5 products a year will receive breakthrough product designation and go onto the new pathway, subject to satisfactory commercial negotiation.” Products are listed as including drugs, devices, digital or diagnostics. Given the specific mention of cancer, dementia and diabetes in the press release we are concerned that rare diseases could miss out.

- There is a heavy emphasis on costs and value for money; the Department of Health talk of “cost-effective breakthrough products.” There is a risk that rare disease drugs could be overlooked as the suggestion is that cost will be a key factor in decision making. For example; “The need to balance our commitment to accelerating patient access to life-changing innovations, against the financial sustainability of the NHS means that accelerated access must be cost neutral for the NHS.”

- The potential use of digital technologies in helping patients is discussed. This links to meetings we have been having with Microsoft exploring new ways to utilise technology to improve the quality of life for disabled people. For example, the possibility of mobile apps replacing alert cards. There is also the suggestion of how technology could be used to help gather real world evidence.

- There is positive mention of streamlining existing access routes to “improve alignment, reduce duplication and grow the commercial capacity of the NHS.” This ties in with Muscular Dystrophy UK’s asks in FastTrack. Department of Health state that they aim to make “significant improvements” in this area by April 2018. One example of that is given is transferring the role of agreeing future Patient Access Schemes from the Department of Health to NHS England.

- The AAC is described as being “pro-innovation.” This links to Muscular Dystrophy UK’s arguments within the FastTrack campaign which calls for innovative approval methods. Furthermore, there is an opportunity for Muscular Dystrophy UK, patients and clinicians to get involved with the AAC which we will be exploring further.
Our next steps to gain clarity over the above points and to make sure rare disease drugs are included in the new Pathway:

- We will be raising the matter in Parliament via Parliamentary questions and will also look to secure a Westminster Hall debate and Roundtable discussion with the Health Minister.
- We will be making an approach to Sir Andrew Witty (who will be chairing the ACC).
- Look to link our clinical networks and outreach teams with NHS RightCare, which is going to be addressing the variation in clinical practice across the country.


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