ACCELERATED ACCESS COLLABORATIVE (AAC) BOARD

Meeting date: 20 March 2024

Paper Title: Preparing for Implementation of Potential New Disease Modifying Treatments (DMTs) for Early Alzheimer's Disease

Agenda item: 5

Report authors: Ann Jarvis, Deputy Director and Programme Director (National Alzheimer's Disease Modifying Treatments Programme), Specialised Commissioning Clinical Team

Paper type: For information and note

AAC Priority Area:

Research	☒	Building innovation capacity	☒
Demand signalling and horizon scanning	☒	Innovator support	☐
Uptake of proven innovation	☐	Cross-cutting (Health Inequalities, Net Zero, Life Sciences Vision)	☒
Other (statutory, governance)	☒		

Ask of the AAC Board:

Receive an update on potential new disease modifying treatments (DMTs) for early Alzheimer's disease, noting in particular the need and opportunities for innovation and further research in this important area.

Executive summary:

Alzheimer's disease is the most common cause of dementia, an umbrella term describing a decline in memory, language and problem solving which eventually significantly impacts on activities of daily living. Whilst historically Alzheimer's treatments have supported the management of disease symptoms, there are currently 28 disease modifying treatments (DMTs) for Alzheimer's disease in late-stage trials for potential launch by 2030.

NHS England has established a national programme to support preparations for the potential implementation of the first two of these medicines (lecanemab and donanemab). These are both monoclonal antibodies, administered intravenously, which are currently going through MHRA and NICE assessment. Subject to positive UK licensing decisions being made, NICE recommendations on potential routine adoption in the NHS may be published from this summer.

Information shared in the recent public board session is provided in an annex to this paper, with a video of the NHSE Board discussion available here.

Background

1. Licensing decisions are currently awaited for two new monoclonal antibodies (lecanemab and donanemab), which may offer 'first in class' disease modifying treatment options for early Alzheimer's disease. NICE appraisals are underway for both medicines in parallel.

2. Excitingly, company trials have demonstrated a slowing of the rate of decline in the earliest stages of symptomatic Alzheimer's disease, by prompting the body's immune response to clear amyloid plaques from the brain. However, there are also potential risks associated with treatment (including brain bleeds, swelling and volume reduction). These first treatments do not yet stop decline, nor offer a cure. Further (ideally comparative) studies are needed to understand the longer-term outcomes of treatments.

3. There is a broader pipeline of DMTs in late-stage trials for potential launch by 2030. These target different elements and stages of the disease process and may also offer different and potentially less intensive and costly options for treatment administration (oral, sub-cut, vaccine).

4. A national programme has been established to support planning and partnership working with other national agencies as the NHS prepares for potential implementation and supports ICBs as the primary commissioners of clinical pathways for dementia.

5. This work sits within the context of a broader national dementia programme and is included within the Major Conditions Strategy. The programme links to, and draws upon, the work of a number of other national programmes. The IRLSS team, for example, is supporting the prioritisation and articulation of remaining evidence gaps with the intention of informing the investment decisions of key research funders, and is also commissioning new horizon scans in digital diagnostics, radiotracers and blood-based biomarkers.

Considerations

6. The national programme is operating in the context of material regulatory uncertainty; MHRA and NICE determinations will be critical to implementation requirements for the NHS.

7. There are also key clinical and service uncertainties, reflecting the first in class nature of these medicines. These include longer term outcome data and the comparative effectiveness and safety of different drugs (or combinations of drugs) in the UK population, as well as the size of the potentially eligible population, and the percentage of patients who might move through each step of the pathway and ultimately choose to take up a treatment offer.

8. The focus on potential new DMTs is casting a wider spotlight on dementia diagnosis and pathways more generally, increasing public awareness and

potentially spurring increased demand for earlier assessment, including interest in more complex diagnostics.

9. New DMT pathways will require significant additional assessment, diagnostic, treatment and monitoring capacity; in some cases impacting on services / specialities remaining in recovery post pandemic.

10. ICBs will be the main commissioners of these pathways, if new DMTs are recommended for use in the NHS by NICE. However, NHS England directly commissions two elements of the pathway: PET-CT scanning and genetic testing (APOE-4). Estimated annual costs of implementation for all elements of the pathway are between £500m to £1bn per full year. The scale of investment required may have a knock-on impact on opportunities for other areas of service improvement.

11. Stakeholder engagement is a key element of the national programme's work. Key partners include other national agencies (NICE, NIHR, DHSC, MHRA, OLS (including the dementia mission)), national charities, and medicines manufacturers. In addition to work with charities and local system partners, there is direct PPV engagement in key work, such as the development of a template clinical access policy.

12. There are known differences in Alzheimer's prevalence, service uptake and outcomes between groups. Inequalities is therefore an important cross-cutting theme of the national programme and opportunities are being taken to both identify and mitigate potential equity, and inequality, risks.

13. Depending on licensing and funding decisions taken in other countries, there may be pressure on supply into the UK (including workforce, medicines, equipment, and radiotracers).

Recommendation

14. It is recommended that AAC board members note and consider the opportunities and challenges in preparing for potential new disease modifying treatments in early Alzheimer's disease.

Next steps

15. The national programme team continues to directly contribute to the NICE appraisals underway for both lecanemab and donanemab, whilst licensing decisions are made by the MHRA. This includes continuing to refine cost, workforce and capacity estimates, working with key national programmes, expert clinical advisors and a range of other stakeholders.

16. As anticipated diagnostic, treatment and safety monitoring costs are likely to be significant, additional funding from the treasury will need to be considered via the spending review process.

17. Works continues on refining the future care pathway for these and other future Alzheimer's DMTs. This includes designing and preparing to stand up new elements of care (for example the introduction of a new stand-alone APOE-4 genetic test) as well as exploring opportunities for innovation (blood-based biomarkers, faster MRI scans) and the mitigation of potential inequalities. Mobilisation planning is in parallel considering the potential recommendation options that NICE may reach, each of which have materially different implications for the NHS.

18. Boosting the programme's work in sharing information and raising awareness amongst different professional groups key to implementation, regional SROs have been confirmed and will be providing additional information and support for ICBs as the primary commissioners of the new diagnostic and treatment pathways that would be required.

19. 'Do once' commissioning products are being developed through a national pathways group with regional and ICB input – this includes a template clinical access policy (covering eligibility, dosing etc) for discretionary adoption by ICBs

20. Work continues with ministers and MPs, system partners and the media to support accurate messaging on the treatments and future decisions on NHS access. This will be critical, for example, at the point a licensing decision is reached but ahead of a NICE recommendation being made.

Board members are asked to:

21. Receive an update on potential new disease modifying treatments for early Alzheimer's disease, noting in particular the need and opportunities for innovation and further research in this important area.