Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Plain language summary of the rapid health technology assessment of immunisation against respiratory syncytial virus (RSV) in Ireland

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Plain language summary

Respiratory syncytial virus (RSV) is a virus that infects the lungs and upper airways. This virus spreads every winter, with the RSV season in Ireland typically running from October to March. In healthy people, infection with RSV can be managed without needing to see a doctor. However, RSV can cause more severe infections in some people, which may lead to them being hospitalised. People at increased risk of severe disease include infants aged under one year, premature babies and children aged under two years with certain medical conditions. Adults aged 65 years and older are also at increased risk of severe disease.

Curently in Ireland, a small number of children who are at high risk of severe disease are offered a drug called palivizumab (Synagis®) to protect them from RSV. Since 2022, a new drug called nirsevimab (Beyfortus®) and two new RSV vaccines have been approved. These can be used to protect infants in the general population and older adults from RSV, not just children who are at high risk. Palivizumab and nirsevimab are not vaccines. They are laboratory-made antibodies which stimulate the immune system, so to provide protection against RSV. While palivizumab has to to be administered monthly during the RSV season, nirsevimab is long-acting, meaning only one dose is needed to protect infants for the RSV season. One of the vaccines can be given to pregnant women — antibodies from the mother transfer to the baby to provide protection from RSV up to six months of age.

In Ireland, nirsevimab (Beyfortus®) will be offered to infants born between September 2024 and February 2025 in a temporary, publicly-funded pilot programme. The Department of Health asked the Health Information and Quality Authority (HIQA) to look at the impact of immunising all infants and older adults with these new drugs to help to inform a decision for the 2025-2026 season. This assessment looked at the benefits and costs to the Health Service Executive (HSE) for differing approaches to immunisation. A larger assessment will be conducted after this assessment is completed, to provide advice for a longer-term policy decision about RSV — this will include the emerging international evidence and evidence from the pilot programme.

We looked to see what other European countries recommend regarding the protection of infants and older adults against RSV. Five of the 31 countries included in this assessment have publicly funded at least one of these new drugs or vaccines to protect infants and or older adults against RSV disease during the 2024-2025 RSV season. Several countries are currently undertaking their own assessment to determine whether they will be funded or not. These national and international

recommendations were informed by results from large randomised controlled trials and real-world evidence from international programmes for the 2023 to 2024 RSV season. This evidence suggests that nirsevimab and the new RSV vaccines are safe and effective in reducing the burden from RSV.

The number of people diagnosed with RSV and the number who require hospitalisation varies from year to year. In 2022, almost 4,000 children in Ireland aged 0 to 4 years tested positive for RSV. Of these, almost 2,500 were admitted to hospital. The majority of these admissions, and almost all ICU admissions, were in children aged less than one year. Most of these hospital admissions happen over a short time period (between October and December). This makes it very challenging for the hospitals and can disrupt routine care (for example, planned surgeries) for other children. In 2022, there were just over 1,500 adults in Ireland aged 65 years and older who tested positive for RSV. Of these, almost 150 were admitted to hospital.

We looked at the cost of immunising different groups of infants and older adults for the 2025-2026 RSV season. For the small number of children at high risk of RSV, we found that it would cost less to switch from palivizumab to the nirsevimab. It would also be more convenient for these families as only one injection would be needed. We found that the cost of immunising infants would range from €3.9 million to €19 million depending on the approach taken. It is expected that these costs would be partially offset by the fact that fewer infants would require hospital care. We found that the cost of vaccinating older adults would be much higher due to the large number of people involved. Offering the vaccine to everyone aged 65 years and older was estimated to cost €146 million, while it would cost €76.2 million if only offered to those aged 75 years and older. As the number of older people who are hospitalised due to RSV is relatively small, the potential cost savings to the HSE from reducing hospital admissions is also small (between €0.9 million and €1.2 million). It is important to note that to calculate these estimates, we have had to assume prices for these drugs, based on known Irish and international prices. If the price of any of these drugs is in fact higher than we have estimated, the costs of immunisation will also be higher. Aside from the cost of providing immunisation to these infant and older adult groups, there would also be additional costs associated with organising any RSV immunisation programme, which we estimated could cost approximately €2.3 million.

In summary, one new drug and two new vaccines have recently been licensed for use in infants and older adults, which may protect them from RSV. However, while the evidence to date indicate that they are safe and effective, the real-world evidence is limited as these are new products. There is still a lot of uncertainty about

the potential costs of these new products and the potential to reduce the burden on the healthcare service.

If the Government decides to fund RSV immunisation and roll out programmes for infants or older adults, there are important things to consider about who might administer these products and where this might happen. For example, if a decision is taken to immunise all infants in their first RSV season, options could include that the roll out is supported by GPs or by special hospital clinics. The timing of administration is also very important. In order to get the best outcomes, some of the products must be given in the weeks before the RSV season begins. Organising the administration of these products to a large number of infants and older adults in this short time frame may be very difficult.

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