ATAGI recommendation for using Trumenba vaccine as a booster dose in individuals at increased risk of invasive meningococcal disease

Individuals of all ages, who are at ongoing risk of invasive meningococcal disease (IMD) due to increased medical risk and/or occupational risks, and who have received a primary course of Trumenba, are recommended to receive a booster dose of Trumenba at 5 years after their previous dose.

Conditions associated with an increased medical risk for IMD include:

- defects in, or deficiency of, complement components, including factor H, factor D or properdin deficiency
- current or future treatment with eculizumab (a monoclonal antibody directed against complement component C5)
- functional or anatomical asplenia, including sickle cell disease or other haemoglobinopathies, and congenital or acquired asplenia
- HIV, regardless of disease stage or CD4+ cell count
- haematopoietic stem cell transplant

There is no current recommendation for subsequent booster doses after the initial single booster dose. The evidence regarding duration of protection after a booster dose will continue to be monitored to guide future recommendations about subsequent booster doses for individuals who remain at ongoing risk.

Justification

- Individuals with increased medical risk of IMD have markedly increased risks of infection which may be lifelong. This can be as high as 10,000 times the risk in the general population for those with genetic deficiencies of the complement pathway. Occupational risk can be ongoing.
- No studies directly assess the optimal timing of booster doses, and the timing recommendation is based only the limited available immunogenicity data. Evidence on duration of protection after the primary schedule, in people at increased medical risk of IMD, against clinical outcomes is not available for Trumenba. Immunogenicity data in healthy individuals suggests early waning of the proportion with hSBA≥1:8 or 1:16 (lower limit of quantitation) after primary vaccination by 12 months with a slower rate of waning subsequently.
- There is very low certainty evidence of a moderate effect from a booster dose of Trumenba, based only on immunogenicity data, which increases the proportion with hSBA≥1:8 or 1:16 (higher than 1:4 the proposed correlate of protection) but the increase varies in size dependent on test strain and on the degree of waning prior to the booster dose. The correlation of protection between an hSBA titre ≥1:4 is more established for serogroup C but there is limited evidence of its applicability for serogroup B disease. There is no evidence available on clinical outcomes after booster doses.
- Despite the very low certainty of evidence, given the increased risk of IMD and the potential severity of infection, the benefits are thought to clearly outweigh the risks of a booster dose which are not of significant concern.
- Evidence of persistence after a booster dose is of very low certainty, and immunogenicity data is limited to ≤2 years after the booster; the rate of waning

appears to vary by strain after booster and may be similar to or slower than after primary vaccination.

Note: NCIRS is conducting GRADE in support of ATAGI and making results available on the NCIRS website. Please read this document as a supplement to the Australian Immunisation Handbook Meningococcal disease chapter