

## Evaluation of and expected access to new RSV vaccines and long-acting monoclonal antibody (mAB) in Australia as at 7 May 2024

RSV vaccine/mAB	Indication	Therapeutic Goods Administration (TGA) approval (registration)	Pharmaceutical Benefits Advisory Committee (PBAC) assessment for funding	National Immunisation Program inclusion/funded supply	Private market supply	Clinical guidance
<b>Infant protection</b>						
<b>Nirsevimab</b> (Beyfortus, Sanofi-Aventis; long-acting monoclonal antibody)	<b>Newborns/infants and children up to 24 months of age with risk conditions</b>	<a href="#"><u>TGA approved in November 2023</u></a>	<a href="#"><u>July 2024</u></a>	<b>State-funded programs:</b> <ul style="list-style-type: none"> <li>• <a href="#"><u>New South Wales</u></a></li> <li>• <a href="#"><u>Queensland</u></a></li> <li>• <a href="#"><u>Western Australia</u></a></li> </ul>	<b>No</b>	<a href="#"><u>ATAGI statement</u></a>
<b>Abrysvo</b> (Pfizer; protein subunit vaccine)	<b>Infants from birth through 6 months of age, by active immunisation of pregnant individuals</b>	<a href="#"><u>TGA approved in March 2024</u></a>	<a href="#"><u>March 2024 – not currently considered cost-effective by PBAC</u></a>	<b>No (PBAC nominated the Early Resolution re-submission pathway for this item)</b>	<b>TBD</b>	<b>TBD</b>

RSV vaccine/mAB	Indication	Therapeutic Goods Administration (TGA) approval (registration)	Pharmaceutical Benefits Advisory Committee assessment for funding	National Immunisation Program inclusion/funded supply	Private market supply	Clinical guidance
<b>Older adult protection</b>						
<b>Abrysvo</b> (Pfizer; protein subunit vaccine)	<b>Adults aged ≥60 years</b>	<a href="#"><u>TGA approved in March 2024</u></a>	TBD	TBD	TBD	TBD
<b>Arexvy</b> (GSK; protein subunit vaccine with adjuvant)	<b>Adults aged ≥60 years</b>	<a href="#"><u>TGA approved in January 2024</u></a>	<a href="#"><u>July 2024</u></a>	TBD	Available	<a href="#"><u>ATAGI clinical statement</u></a>
<b>Moderna</b> (Moderna RSV mRNA-1345 vaccine)	<b>Adults aged ≥60 years</b>	<a href="#"><u>Submitted</u></a>	TBD	TBD	TBD	TBD