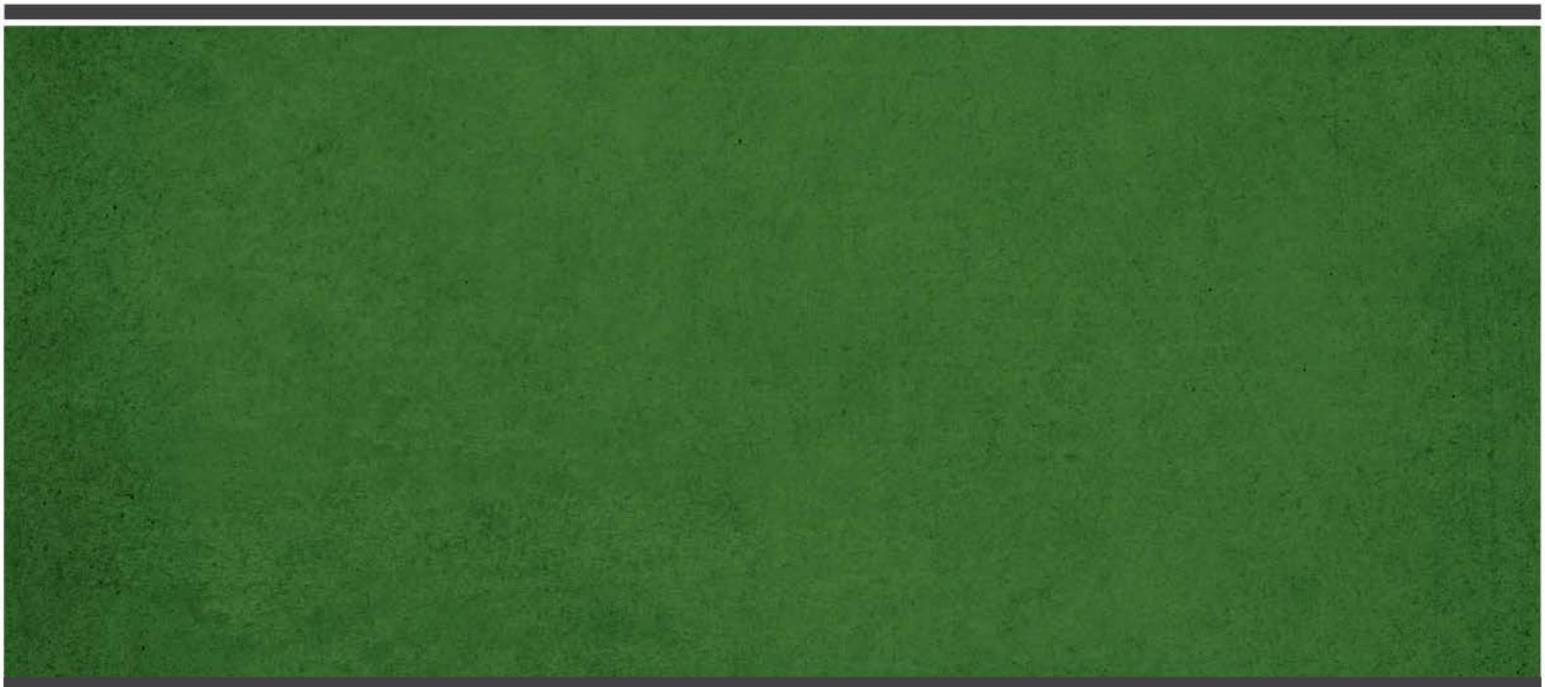
An Advisory Committee Statement (ACS)

National Advisory Committee on Immunization (NACI)

Statement on the prevention of respiratory syncytial virus (RSV) disease in infants: Supplementary systematic review of economic evidence



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Preamble

The National Advisory Committee on Immunization (NACI) is an External Advisory Body that provides the Public Health Agency of Canada (PHAC) with independent, ongoing and timely medical, scientific, and public health advice in response to questions from PHAC relating to immunization.

In addition to burden of disease and vaccine characteristics, PHAC has expanded the mandate of NACI to include the systematic consideration of programmatic factors in developing evidence based recommendations to facilitate timely decision-making for publicly funded vaccine programs at provincial and territorial levels.

The additional factors to be systematically considered by NACI include: economics, ethics, equity, feasibility, and acceptability. Not all NACI statements will require in-depth analyses of all programmatic factors. While systematic consideration of programmatic factors will be conducted using evidence-informed tools to identify distinct issues that could impact decision-making for recommendation development, only distinct issues identified as being specific to the vaccine or vaccine-preventable disease will be included.

This statement contains NACI's independent advice and recommendations, which are based upon the best current available scientific knowledge. This document is being disseminated for information purposes. People administering the vaccine or monoclonal antibody should also be aware of the contents of the relevant product monograph. Recommendations for use and other information set out herein may differ from that set out in the product monographs of the Canadian manufacturers of the vaccines. Manufacturer(s) have sought approval of the vaccines and provided evidence as to its safety and efficacy only when it is used in accordance with the product monographs. NACI members and liaison members conduct themselves within the context of PHAC's Policy on Conflict of Interest, including yearly declaration of potential conflict of interest.

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Overview of economic evidence

Systematic reviews and a *de novo* model-based cost-utility analysis were used as economic evidence to support decision-making for the use of a bivalent RSV prefusion F protein–based (RSVpreF) vaccine and a long-acting monoclonal antibody (nirsevimab) in pregnant women and infants, respectively, for the prevention of RSV-related outcomes in the pediatric population. The systematic reviews are published [1, 2], and summarized below, along with an additional review of the grey literature. Details of the model-based cost-utility analysis are published elsewhere [3]. All costs are reported in 2023 Canadian dollars unless otherwise specified.

A note on language:

NACI recognizes that not all people giving birth or breastfeeding will identify as women or mothers. Much of the research available currently refers only to "women" when discussing pregnancy. When citing research, NACI refers to the language used in the study. In these cases, "woman" refers to someone who was assigned female at birth and "maternal" is used to identify the person who is pregnant or postpartum. For the purposes of this statement, the terms "woman," "women," and "maternal" should be considered to also apply to those individuals who do not specifically identify as female gender but are the parent gestating the fetus or breastfeeding or chestfeeding the infant.

Systematic reviews of economic evaluations

Separate systematic reviews were conducted for the cost-effectiveness of (i) RSV immunization during pregnancy to prevent RSV outcomes in infants and women who are pregnant, and (ii) nirsevimab in infants. The peer-reviewed literature searches were updated May 8, 2023, and June 13, 2023, respectively. The grey literature search was updated November 15, 2023. The included studies were limited to high income countries and to studies published in English or French.

I. Summary of included studies

Table 1 summarizes the six studies included in the systematic reviews [4-9], and the five models included in the grey literature review [10-15]. Note that the grey literature review accepted preprints and slide decks presented to National Immunization Technical Advisory Groups. Other grey literature such as conference abstracts, poster presentations and presentations on multi-model comparisons were not included, as methods and results were not sufficiently reported. The study settings were in Europe (N = 4) [4, 5, 8, 10], USA (N = 5) [7, 9, 11-14], and Canada (N = 2) — one reflective of the Canadian Arctic region (Nunavik) [6], and one reflective of the Canadian south [15]. All studies were published between 2013 to 2023.

All studies used a health system perspective, while three studies had additional analyses using a societal perspective — namely through the inclusion of productivity loss of parents from paid employment to care for a child with RSV and/or to receive an RSV intervention [4, 9, 15]. In addition to productivity loss in the societal perspective, Shoukat et al. also included the monetary loss of life due to infant mortality [15], Regnier included out-of-pocket costs for travel, meals, and lodging [9], and Getaneh et al. included loss of leisure time [4]. In terms of study quality, all studies met more than 50% of the Joanna Briggs Institute (JBI) Critical Appraisal Checklist criteria [16]. All studies reported incremental cost-effectiveness ratios (ICERs) with the exception of Kieffer et al., which reported medical costs saved due to reductions in healthcare use from RSV prophylaxis [7]. Two studies conducted sequential analyses, where authors compared three or more interventions in one analysis, unlike in traditional cost-effectiveness analyses where there are only two interventions compared (pair-wise) [4, 5]. Six studies conducted threshold analyses for product prices, where authors determined at what

price an intervention became cost-effective under specific cost-effectiveness thresholds [4, 5, 8-10, 15]. Two studies reported industry funding [7, 9], and one study reported private and public funding with no involvement from the funders [8].

II. Model-specific appraisal

Three studies modelled RSV transmission, allowing for indirect effects such as community immunity to be captured [6, 8, 10]. Given the uncertain causal relationship between RSV and asthma or wheezing, most models excluded these sequelae with the exception of Regnier (odds ratio of asthma or wheezing = 3.84 [95% CI: 3.23 to 4.58] until 10 years of age) and Shoukat et al. (probability of wheezing post-hospitalization = 0.31; duration = 5.2 to 9.8 days) [9, 15]. Only one study included product wastage (5%) [6]. Several studies did not include RSV-related mortality [4, 6]. Those that did took different approaches: per-infection probability of death (range: 0.0008197% to 0.0054%) [7-10]; and post-hospitalization probability of death (range: 0.02% to 3.3%) [11-15].

For the included studies in the systematic reviews, the pregnancy vaccines assessed were not all specific to RSVpreF, with some studies evaluating theoretical maternal vaccines. The vaccine efficacies used ranged from 24.7% to 70%. Several studies used the World Health Organization's Preferred Product Characteristics (i.e., 70% efficacy lasting at least 4 months). In contrast, most studies assessed nirsevimab specifically (e.g., using MELODY clinical trial data) as opposed to a generic long-acting monoclonal antibody.

Several studies reported threshold analyses of product prices as their main results; hence they varied prices over a large range, with lower bounds likely beyond the range of plausible discounted prices, at least in the Canadian context. Of note, the study on the Canadian south assessed prices between $50 to $1,000 for both immunization products [15]. The England and Wales studies to support JCVI deliberations assessed prices from approximately $2 to $7,800 (£1 to £4,600) for nirsevimab [8], and from approximately $0 to $340 (£0 to £200) for a pregnancy vaccine [10]. Among studies that did not conduct threshold analyses as their main results (i.e., studies that assumed one product price in the base case analysis), notable long-acting monoclonal antibody prices include: $1,065 to $2,048 per dose in the Canadian Arctic region [6], and approximately $690 (500 USD) per dose in the United States [12]. Notable pregnancy vaccine prices include: $1,560 per dose in the Canadian Arctic region [6], and approximately $408 (295 USD) per dose in the United States [13].

Table 1: Summary of included studies (N = 11) in systematic reviews of economic evaluations and grey literature review

	Setting	Perspective(s)	Time horizon	Interventions and comparators[a]	RSV transmission	Sequential ICERs	Threshold analysis for price	Industry funding?
Nourbask 2022 (6)	Nunavik, Quebec, Canada	Health system	1 year	☑ Nirsevimab ☑ Pregnancy vaccine ☑ Combined products ☑ Palivizumab ☑ No intervention	✓			
Shoukat 2023 (15)	Canadian South	Health system, Societal[b] (+monetary loss of life due to infant mortality)	1 year	☑ Nirsevimab ☑ Pregnancy vaccine ☑ Combined products ☐ Palivizumab ☑ No intervention			✓	
Getaneh 2023 (4)	Denmark, England, Finland, Italy (Venato), The Netherlands, Scotland	Health system, Societal[b] (+loss of leisure time)	5 years	☑ Nirsevimab ☑ RSVpreF ☐ Combined products ☑ Palivizumab ☑ No intervention		✓	✓	

Li 2022 [5]	Norway	Health system	5 years	☑ Nirsevimab ☑ Pregnancy vaccine ☐ Combined products ☐ Palivizumab ☑ No intervention		✓	✓	
Hodgson 2022 [8]	England and Wales	Health system	10 years	☑ Nirsevimab ☐ Pregnancy vaccine ☐ Combined products ☑ Palivizumab ☐ No intervention	✓		✓	✓ (mix of public; funders not involved with study)
Hodgson 2023 [10]	England and Wales	Health system	10 years	☑ Nirsevimab ☑ RSVpreF ☐ Combined products ☐ Palivizumab ☐ No intervention	✓		✓	
Kieffer 2022 [7]	USA	Health system	6 months	☑ Nirsevimab ☐ RSVpreF ☐ Combined products ☑ Palivizumab				✓

				☐ No intervention				
Regnier 2013 (9)	USA	Health system, Societal[b] (+travel, meals, lodging)	5 years	☐ Nirsevimab ☑ Pregnancy vaccine ☐Combined products ☑ Palivizumab ☐ No intervention			✓	✓
Hutton 2023 (Nirsevimab) (11, 13)	USA	Health system	1 year	☑ Nirsevimab ☐ Pregnancy vaccine ☐Combined products ☑ Palivizumab ☑ No intervention				
Hutton 2023 (RSVpreF) (12, 14)	USA	Health system	1 year	☐ Nirsevimab ☑ Pregnancy vaccine ☐Combined products ☑ Palivizumab ☐ No intervention				
Hutton 2023 (Combined	USA	Health system	1 year	☐ Nirsevimab ☐ Pregnancy vaccine				

products) (13, 14)				☑ Combined products ☑ Palivizumab ☐ No intervention				

[a] Interventions and comparators: Not every product was compared to one another
[b] Societal perspective: Defined by studies as the inclusion of productivity loss of parents from paid employment to care for a child with RSV and/or to receive an RSV intervention
Combined products: Refers to combination of a long-acting mAb and a pregnancy vaccine
Abbreviations: ICER = incremental cost-effectiveness ratio; mAb = monoclonal antibody

III. Summary of results

Summaries of each peer-reviewed study from the systematic reviews can be found in the original reports [1, 2]. Note that the included studies used a range of model inputs and assumptions (e.g., vaccine efficacies), took place in different settings (e.g., Canadian Arctic or South, Europe, USA), and modelled different implementation strategies (e.g., seasonal versus year-round). As most studies used the health system perspective, the ICERs reported below are from this perspective unless otherwise stated.

1. Pregnancy vaccines versus no intervention (N = 4 studies using pairwise or sequential analyses):

   ICERs ranged widely: In Finland and in the Nunavik setting during moderate and severe RSV seasons (i.e., more than 50% of households infected with RSV), the estimated ICERs were dominant (i.e., less costly, more effective) [4, 6]. In the Netherlands, Norway, and in the Nunavik setting during mild RSV seasons, ICERs were over $200,000 per quality-adjusted life-year (QALY) [4-6].

2. Nirsevimab versus no intervention (N = 1 study using pairwise or sequential analyses):

   ICERs ranged within the same Nunavik setting, depending on severity of the RSV season: During moderate and severe RSV seasons, nirsevimab in high-risk infants was dominant (i.e., less costly, more effective) compared to no intervention. High-risk infants were defined as preterm infants and chronically ill infants under 1 year of age (i.e., underlying comorbidities, such as chronic lung disease and hemodynamically significant heart disease). During a mild season, the ICER was over $200,000 per QALY [6].

3. Nirsevimab versus palivizumab (N = 1 study using pairwise or sequential analyses):

   In Nunavik, replacing palivizumab with nirsevimab among high-risk infants (i.e., preterm or chronically ill infants under 1 year of age) was dominant (i.e., less costly, more effective) [6]. Expanding nirsevimab to healthy infants aged 0 to 2 months in addition to high-risk infants had ICERs ranging from dominant during a severe RSV season to $39,414 per QALY during a mild season when compared to palivizumab [6].

4. Pregnancy vaccines versus nirsevimab (N = 2 studies using pairwise or sequential analyses):

   Pregnancy vaccines were consistently dominated (i.e., more costly, less effective) by seasonal programs of nirsevimab with or without a catch-up – regardless of setting (Denmark, England, Finland, Italy [Venato], The Netherlands, Scotland, Norway) [4, 5].

5. Combined products versus palivizumab (N = 1 study using pairwise or sequential analyses):

   In Nunavik, a pregnancy vaccine program combined with nirsevimab use in preterm or chronically ill infants aged 3 to 11 months was dominant (i.e., less costly, more effective) compared to palivizumab in healthy infants aged 0 to 2 months [6].

Below is a high-level summary of the additional studies included in the grey literature review:

1. The economic evaluation of nirsevimab by Hutton et al. in the US setting found a base case ICER of approximately $215,645 per QALY (or 157,537 USD per QALY) when comparing an all-infant program to "natural history" (which was a strategy that included the cost of palivizumab for high-risk infants) [11, 13]. The product price plus administration was approximately $690 (500 USD) per dose, efficacy was taken from the MELODY trial data, and coverage was 50%. Cost-effectiveness results were robust when varying efficacy in months 6 to 10 (from 0% to 50%) and when varying seasonality of program (October to February, March or April). ICERs hovered around approximately $191,540 per QALY (or 140,000 USD per QALY) using an optimistic 50% efficacy assumption across different seasonal programs. The ICERs reported are from a societal perspective.

2. The economic evaluation of RSVpreF by Hutton et al. in the US setting found a base case ICER of approximately $547,555 per QALY (or 400,304 USD per QALY) when comparing year-round vaccination with no intervention [12, 14]. The product price plus administration was approximately $408 (295 USD) per dose, and coverage was 50%. Cost-effectiveness results were robust when varying coverage. ICERs remained high when varying vaccine efficacy assumptions: approximately $500,300 per QALY (or 365,669 USD per QALY) using a flat efficacy of 57.1% against medically-attended lower respiratory tract infections and 56.8% against RSV-associated hospitalizations up until 6 months. When using more optimistic efficacy assumptions (higher and longer protection), the ICERs reduced slightly to approximately $391,480 per QALY (or 286,179 USD per QALY). In scenario analyses where seasonal pregnancy programs were explored, cost-effectiveness results were sensitive to months of administration. The lowest ICERs were observed for programs vaccinating from September to January and September to December (approximately $228,830 and $194,030 per QALY [or 167,280 USD and 141,806 USD per QALY] respectively). The probability of prematurity was a very influential factor that could drive the ICERs up to $1.3 million USD per QALY. The ICERs reported are from a societal perspective.

3. The combined products economic evaluation by Hutton et al. in the US setting assessed administering RSVpreF to all pregnant women people and nirsevimab to all infants (e.g., administered at time of birth when born October to March; administered as catch-up dose in October or November when born April to September) as the base case [13, 14]. When compared to "natural history" (which was a strategy that included the cost of palivizumab for high-risk infants), the ICER was approximately $915,490 per QALY (or 668,735 USD per QALY). In an analysis of administering RSVpreF to all pregnant women and nirsevimab only to babies born out of the RSV season (i.e., born April to September; administered as a catch-up dose in October or November), the ICER was $666,150 per QALY (or 486,882 USD per QALY). The ICERs reported are from a societal perspective.

4. Shoukat et al. assessed the use of nirsevimab, RSVpreF vaccine, and both products in combination in the Canadian South [15]. Seasonal nirsevimab programs with catch-up targeting various populations were assessed: (i) preterm infants 32 weeks of gestational age (wGA) or less and infants with chronic lung disease (CLD) or congenital heart disease (CHD); (ii) preterm infants 36 wGA or less and infants with CLD or CHD condition; (iii) preterm infants 36 wGA or less, infants with CLD or CHD, and term infants born during RSV season; and (iv) all infants. The comparator was palivizumab use in high-risk infants. The pregnancy program assessed was year-round. The combined products program was year-round vaccination of pregnant women followed by administration of nirsevimab to infants at high-risk of

severe RSV disease (i.e., preterm infants 32 wGA or less and infants with CLD or CHD condition) during the RSV season. In the base case analysis, all programs had 100% coverage. The main findings were presented as threshold analyses on price, assessing the maximum product price in order for programs to be considered cost-effective under a threshold of $50,000 per QALY. Shoukat et al. varied the price of both products from $50 to $1,000 per dose and used an administration cost of $15. The following maximum prices were noted for the corresponding nirsevimab programs above: (i) $615; (ii) $375; (iii) $300; and (iv) $215. The maximum price for a RSVpreF vaccine was $160 in a standalone year-round program. In a combined products program, the maximum price for RSVpreF would be $140 if the price for nirsevimab was $615 per dose; and $155 if nirsevimab price was reduced to $215 per dose. Under a societal perspective, the maximum product prices were all higher, driven by the inclusion of productivity loss of parents.

5. Hodgson et al. (2023) directly compared nirsevimab to RSVpreF in the England and Wales setting [10]. The nirsevimab programs assessed were: (i) seasonal program administered between September and February; (ii) seasonal program administered between September and February with a catch-up dose in September for infants born out of the RSV season; and (iii) year-round program. Coverage was 90%. The pregnancy programs assessed were: (i) seasonal program administered between July and December for women who are 24 to 36 weeks pregnant; and (ii) year-round program. Coverage was 60%. The main findings were threshold analyses on maximum product prices (including administration costs) in order for programs to be considered cost-effective under a threshold of approximately $51,100 per QALY (or £30,000 per QALY). Hodgson et al. found that if nirsevimab were priced above approximately $143 (or £84), then a seasonal pregnancy program would be optimal between approximately $61 to $136 (or £36 to 80), and a year-round pregnancy program would be optimal up to $60 (or £35). Cost-effectiveness results were robust to varying coverage assumptions.

IV. Discussion

In many settings, programs using nirsevimab alone, RSVpreF alone, or in combination generated ICERs that generally exceeded commonly used cost-effectiveness thresholds. Dominant results (i.e., programs being less costly and more effective) were seen under very specific conditions. For instance, in the Nunavik setting during mild RSV seasons (i.e., 30 to 50% of households had individuals infected with RSV), the pregnancy vaccine had an ICER above $200,000 per QALY [6]. During moderate or severe RSV seasons (i.e., more than 50% of households had individuals infected with RSV), a pregnancy vaccine program (not specific to RSVpreF) was dominant (i.e., less costly and more effective) compared to no intervention. Nirsevimab programs for infants at high-risk, with or without a pregnancy vaccine program were dominant compared to no intervention, regardless of the severity of the RSV season [6]. In studies that conducted pricing threshold analyses, the product prices needed to be low in order for programs to be cost-effective. For instance, the study on the Canadian South estimated that RSVpreF needed to be below $160 per dose, and nirsevimab needed to be $215 per dose for an all-infant program, and between $300 to $615 for various high-risk infant programs [15]. The study on England and Wales assessed nirsevimab prices of approximately $143 per dose (or £84), and if priced any higher, pregnancy vaccine programs would be more cost-effective [10]. The maximum prices estimated by these studies differ from the prices used in the USA in support of Advisory Committee on Immunization Practices (ACIP) recommendations – approximately $690 (500 USD) per dose for an all-infant program in the

United States. Note that the ACIP has recommended the use of nirsevimab for all infants aged less than 8 months born during or entering their first RSV season, and for infants and children aged 8 to 19 months who are at increased risk of severe RSV disease entering their second RSV season [17]. ACIP has also recommended the use of RSVpreF for persons 32 to 36 weeks pregnant using seasonal administration (meaning September to January in most of the United States) [18]. Similarly, JCVI recommended an RSV immunization program that is cost-effective should be developed for infants. Both products were recommended, and no preference was placed for a particular product [19].

Overall, the variation across study findings is due to the wide variation in model inputs. For instance, many of the peer-reviewed studies were conducted when product prices and clinical trial data for RSVpreF were not yet available, and different assumptions were used. Further, the settings varied, and there may be underlying differences between modelled countries in terms of 1) their RSV burden, and 2) their health care system organization. Only two studies were directly generalizable to the Canadian context [6, 15]. The implementation of the programs (i.e., offered seasonally versus year-round; offered with a nirsevimab catch-up dose versus none; offered to all versus subpopulations) also impacted cost-effectiveness. Influential parameters affecting cost-effectiveness results included: effectiveness and duration of protection assumptions, QALY decrement assumptions, severity of RSV season, and product prices.

Note that inclusion criteria were of cost-effectiveness studies, and the literature searches did not search for budget impact. Provinces and territories may benefit from conducting budget impact analyses to examine the financial impact of relevant immunization strategies within their own budgets.

List of Abbreviations

ACIP	Advisory Committee on Immunization Practices
CHD	Congenital heart disease
CLD	Chronic lung disease
ICER	Incremental cost-effectiveness ratio
JBI	Joanna Briggs Institute
JCVI	Joint Committee on Vaccination and Immunisation
mAb	Monoclonal antibody
NACI	National Advisory Committee on Immunization
PHAC	Public Health Agency of Canada
QALY	Quality-adjusted life year
RSV	Respiratory syncytial virus
wGA	Weeks of gestational age

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