ADULT IMMUNIZATION

CHI Formulary Indication Review

March 2025

PREPARED FOR:

Council of Health Insurance

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Related Documents

Related SOPs

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- IDF-FR-WI-01-01SearchMethodologyGuideForNewIndications

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Abbreviations

ACIP	Advisory Committee on Immunization Practices
AIDS	Acquired Immune Deficiency Syndrome
aIIV4	Quadrivalent Adjuvanted Inactivated Influenza Vaccine
ALT	Alanine Transaminase
AST	Aspartate Transaminase
BCG	Bacillus Calmette-Guerin
bDMARDs	biological DMARDs
CDA	Canada's Drug Agency
CAR-T-Cell Therapy	Chimeric Antigen Receptor T-Cell Therapy
CD4	Clusters of Differentiation 4
CHI	Council of Health Insurance
COVID-19	Corona Virus Disease Of 2019
CSF	Cerebrospinal Fluid
CYD-TDV	Tetravalent, Live Attenuated, Chimeric Dengue Vaccine
DDF	Daman Drug Formulary
DMARDs	Disease-Modifying Antirheumatic Drugs
EZV	Ebola Zaire vaccine
GBS	Guillain-Barré syndrome
GMT	Geometric Mean Titers
HAS	Haute Autorité de Santé
HAV	Hepatitis A Virus
HbsAg	Hepatitis B Surface Antigen
HBV	Hepatitis B Virus
HCT	Hematopoietic Cell Transplant
HCV	Hepatitis C Virus
HD-IIV4	High-Dose Inactivated Influenza Vaccine
HepB	Hepatitis B
HIV	Human Immunodeficiency Virus
HPV	Human Papilloma Virus
HTA	Health Technology Assessment
ID	Intradermal
IGRA	Interferon Gamma Release Assay Test
IIV4	Quadrivalent Inactivated Influenza Vaccine
IM	Intramuscular
IM	Intramuscular
IPV	Inactivated Polio Vaccine
IQWIG	Institute for Quality and Efficiency in Health Care
LAIV4	Quadrivalent Live Attenuated Intranasal Vaccine
MCV	Meningococcal Vaccine

MenACWY	Meningococcal ACWY
MenB	Meningococcal B
MenC	Meningococcal C
MIS-A	Multisystem Inflammatory Syndrome In Adults
MIS-C	Multisystem Inflammatory Syndrome In Children
MMR	Measles, Mumps, Rubella
mRNA	messenger Ribonucleic Acid
NICE	National Institute for Health and Care Excellence
OCV	Oral Cholera Vaccine
PBAC	Pharmaceutical Benefits Advisory Committee
PCV	Pneumococcal Conjugate Vaccine
PEP	Postexposure Prophylaxis
PHA	Public Health Authority
PPSV23	Pneumococcal Polysaccharide
PrEP	Pre-Exposure Prophylaxis
RABV	Rabies Virus
RCV	Rubella Containing Vaccine
RIG	Rabies Immune Globulin
RIV4	Quadrivalent Recombinant Influenza Vaccine
RZV	Recombinant Zoster Vaccine
TCV	Typhoid Conjugate Vaccine
Td	Tetanus, diphtheria
Tdap	Tetanus, diphtheria, and acellular pertussis
TNF	Tumor Necrosis Factor
TOPV	Trivalent Oral Polio Vaccine
tsDMARDs	targeted synthetic DMARDs
TST	Tuberculin Skin Test
TTCV	Tetanus Toxoid Containing Vaccine
Ty21a	Typhoid Vaccine Live Oral
USPSTF	United States Preventive Services Task Force
VAR	Varicella Vaccine
VE	Vaccine Efficacy
ViPS	Vi Capsular Polysaccharide Vaccine
VPD	Vaccine Preventable Diseases
WC Vaccines	Shanchol, Euvchol, and mORCVAX
WC-rBS	Dukoral
WHO	World Health Organization
YF	Yellow Fever
ZVL	Zoster Vaccine Live

Executive Summary

Vaccination is defined as the act of introducing a vaccine into the body to produce protection from a specific disease. Immunization is the process by which a person becomes protected against a disease through vaccination. This term is often used interchangeably with vaccination or inoculation[1].

Immunization successfully uses immunotherapy to treat many infectious diseases by stimulating the immune system to produce specific antibodies or specific lymphocytes to fight off pathogens and, more recently, protect against malignant tumors. This immunotherapy creates an immunological memory that can be long-lasting[2].

The primary focus of vaccination programs has historically been directed to childhood immunizations (≤ 18 years of age). For adults (≥ 19 years of age), chronic diseases have been the primary focus of preventive and medical health care, though there has been increased emphasis on preventing infectious diseases. Adult vaccination coverage, however, remains low for most of the routinely recommended vaccines[3]. As the burden of vaccine-preventable disease (VPD) shifts to older individuals, protecting adults against influenza, pneumococcal disease, herpes zoster, and other VPDs is part of an effective strategy for curbing adult morbidity and mortality, reducing disability, improving quality of life, and protecting against the emergence of antimicrobial resistance, an issue of particular concern for older adults. Disease burden modeling conducted by the Institute for Health Metrics and Evaluation suggested three priority VPDs – influenza lower respiratory tract infections, pneumococcal pneumonia and meningitis, and herpes zoster – were responsible for approximately one in every five communicable disease deaths and Disability-adjusted Life Years among adults aged ≥ 60 years in 2017[4].

As per Carrico et al., current adult vaccination coverage (vs. no vaccination) is estimated to result in nearly 65 million averted disease cases, $185 billion averted costs of cases, and $136 billion in incremental vaccination costs over a 30-year period from a societal perspective (Benefit-cost ratio = 1.4)[5].

The common barriers to immunization in adulthood include lack of recognition of the importance of adult immunization, lack of recommendation from health care providers, misrepresentation/misunderstanding of the risks of vaccine and benefits of disease prevention in adults, lack of publicly funded vaccine and reimbursement to vaccine providers, and lack of coordinated immunization programs for adults to name a few[6].

CHI issued the Adult Immunization clinical guidance after thorough review of renowned international and national clinical guidelines in February 2020. Updating clinical practice guidelines (CPGs) is a crucial process for maintaining the validity of recommendations.

This report functions as an addendum to the prior CHI Adult Immunization clinical guidance and seeks to offer guidance for Adult Immunization. It provides an **update on the Adult Immunization Guidelines** for CHI Formulary with the ultimate objective of updating the DDF (Daman Drug Formulary) while addressing **the most updated best available clinical and economic evidence related to vaccines.** This formulary is intended to assist in coverage decisions and does not replace the clinical judgment of treating healthcare providers but complements their decision-making process. It is a dynamic resource, updated regularly based on emerging evidence.

Main triggers for the update are summarized, being **the issuance of updated versions of previously reviewed guidelines** as the 2025 Center for Disease Control and Prevention (CDC) Immunization Schedule for Adults and the 2025 UK Immunization Schedule. **New guidelines are added to the report** such as the 2023 Saudi Preventive Guideline, the 2024 WHO Routine Immunization Schedule, the 2024 Australian National Immunization Program Schedule, and the 2025 Canada's Improving Adult Immunization. Other triggers include **newly approved SFDA registered vaccines** as the Vaxneuvance® Pneumococcal 15-Valent Conjugate Vaccine, Prevnar 20® Pneumococcal Conjugate Vaccine, Arexvy® and Abrysvo® Respiratory Syncytial Virus Vaccine, and Gardasil® 9 Human Papilloma Virus Vaccine, **newly approved non-SFDA registered vaccines** as Nuvaxovid® and Covovax® COVID-19 Vaccines, PreHevbrio® Hepatitis B Vaccine, MenQuadfi® Meningococcal Vaccine, Penbraya® Meningococcal Vaccine, Capvaxive® Pneumococcal Conjugate Vaccine and Mresvia® Respiratory Syncytial Virus Vaccine and **updated safety recommendations and special considerations.**

All recommendations are well supported by reference guidelines, Grade of Recommendation (GoR), Level of Evidence (LoE) and Strength of Agreement (SoA) in all tables reflecting specific vaccines' role in the implementation of Adult Immunization.

Major recommendations for newly suggested immunizations are summarized in the table below:

For SFDA Registered Vaccines:

Table 1. New SFDA-Registered Vaccine Recommendations

Vaccine	Indication	Level of Evidence/ Recommendation	HTA Recommendations
Vaxneuvance® (Pneumococcal 15-Valent Conjugate Vaccine)	Prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F	Strong Recommendation[9]	No HTA recommendations have been issued for Vaxneuvance®.
Arexvy® (Respiratory Syncytial Virus Vaccine, Adjuvanted)	Prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in individuals 60 years of age and older and in individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV.	Strong Recommendation[10]	Positive recommendation from HAS[11]. Negative recommendation from PBAC[12] and further study is required by CDA[13].
Abrysvo® (Recombinant respiratory syncytial virus vaccine (RSVPreF))	Prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in persons ≥ 60 years of age and in persons 18 to 59 years of age who are at increased risk of LRTD caused by RSV.	Strong Recommendation[14]	Positive recommendation from HAS for pregnant women[15]. Further studies required for pregnancy-specific vaccination as per CDA[16]. Negative recommendation for pregnancy-

	To be given to pregnant patients at 32 through 36 weeks' gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age.		specific vaccination as per PBAC[17].
Prevnar 20® (20-valent Pneumococcal Conjugate Vaccine)	Prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F. Prevention of pneumonia caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F.	Strong Recommendation[18]	Positive recommendation from HAS[19] and PBAC[20].
Gardasil® 9 (Human Papillomavirus 9-valent Vaccine, Recombinant)	Prevention of 9 Human Papillomavirus serotypes 6.11.16.18,31.33.45.52 and 58 Prevention of HPV-related cancers (Cervical, vulvar and vaginal cancer in	Strong Recommendation[14]	Positive recommendation from HAS[21] and PBAC [22].

	women and penile cancer in men and anal cancer and oropharyngeal cancer in both sexes)		

For Non-SFDA Registered Vaccines:

Table 2. New Non-SFDA Registered Vaccine Recommendations

Vaccine	Indication	Level of Evidence/ Recommendation
Comirnaty® (COVID-19 Vaccine, mRNA)	COVID-19 Prevention	Strong Recommendation[7]
Nuvaxovid® and Covovax® – Novavax	COVID-19 Prevention	Strong Recommendation[7]
PreHevbrio® (Hepatitis B Vaccine, Recombinant)	Hepatitis B Virus Prevention	Strong Recommendation[23]
MenQuadfi® (Meningococcal [Groups A, C, Y, W] Conjugate Vaccine)	Prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W, and Y.	Strong Recommendation[24]
Penbraya® (Meningococcal Groups A, B, C, W, and Y Vaccine)	Prevention of invasive disease caused by Neisseria meningitidis serogroups A, B, C, W, and Y.	Strong Recommendation[25]
Mresvia® (Respiratory syncytial virus mRNA vaccine)	Protection of adults aged 60 years and older from lower respiratory tract disease caused by RSV infection.	N/A
Capvaxive® (Pneumococcal 21-Valent Conjugate Vaccine)	Prevention of invasive pneumococcal disease and pneumococcal pneumonia in adults.	N/A

Section 1.0 Summary of Reviewed Clinical Guidelines and Evidence

This section is divided into two parts; the first includes recommendations from **updated versions of guidelines** mentioned in the previous CHI Adult Immunization report, and the second includes **newly added guidelines** that have helped generate this report.

1.1 Revised Guidelines

The following segment contains the updated versions of the guidelines mentioned in the February 2020 CHI Adult Immunization Report and the corresponding recommendations:

Table 3. Guidelines Requiring Revision

Guidelines Requiring Revision	
Old Versions	**Updated versions**
Center for Disease Control and Prevention (CDC) Immunization Schedule for Adults **[2020]**	Center for Disease Control and Prevention (CDC) Immunization Schedule for Adults **[2025]**
UK Immunization Schedule **[2020]**	UK Immunization Schedule **[2025]**

1.1.1 Center for Disease Control and Prevention (CDC) Immunization Schedule for Adults [2025]

The following guidelines do not provide a specified grade of evidence or level of recommendation.

*Please refer to **Section 1.1** of the CHI Adult Immunization Report Version 2.*

The CDC has issued a 2025 updated vaccination schedule along with recommendations for the optimization of Adult Immunization; the recommendations are detailed below[2627]:

COVID-19 Vaccination for People Who Are Not Moderately or Severely Immunocompromised:

Routine Vaccination:

- **Unvaccinated:**
    - 1 dose 2024–25 Moderna or Pfizer-BioNTech

    - 2 doses 2024–25 Novavax at 0, 3–8 weeks
- **Previously vaccinated before 2024–25 vaccine with:**
    - **1 or more doses Moderna or Pfizer-BioNTech:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech at least 8 weeks after the most recent dose.
    - **1 dose Novavax:** 1 dose 2024–25 Novavax 3–8 weeks after most recent dose. If more than 8 weeks after most recent dose, administer 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech.
    - **2 or more doses Novavax:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech at least 8 weeks after the most recent dose.
    - **1 or more doses Janssen:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech.

Age 65 years and older:

- **Unvaccinated:** Follow recommendations above for unvaccinated persons ages 19–64 years **and** administer dose 2 of 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months).
- **Previously vaccinated before 2024–25 vaccine:** Follow recommendations above for previously vaccinated persons ages 19–64 years **and** administer dose 2 of 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months).

Of note, there is no preferential recommendation for the use of one COVID-19 vaccine over another when more than one recommended age-appropriate vaccine is available.

- An 8-week interval between the first and second mRNA COVID-19 vaccine (Moderna, Pfizer-BioNTech) doses and between the first and second doses of Novavax COVID-19 Vaccine might be optimal for some people as it might reduce the rare risk of myocarditis and pericarditis associated with these COVID-19 vaccines.
- The minimum interval between the first and second doses continues to be recommended for people who are moderately or severely immunocompromised, people aged 65 years and older receiving Novavax vaccine, and in situations when the fullest possible protection needs to be achieved sooner (e.g., increased concern about an individual's higher risk for severe disease).
- The following table describes the recommended COVID-19 Vaccination Schedule for patients who are not moderately or severely immunocompromised:

Table 4. Recommended COVID-19 Vaccination Schedule for Patients Who Are Not Moderately or Severely Immunocompromised Ages 12-64 Years

COVID-19 vaccination history before 2024–2025 vaccine*†	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine‡ and interval between doses
Unvaccinated: • Initiate vaccination with 2024–2025 vaccine		
Unvaccinated	1	**2024–2025 Dose 1** (Moderna or Pfizer-BioNTech): Day 0
	OR	
	2	**2024–2025 Dose 1** (Novavax): Day 0 **2024–2025 Dose 2** (Novavax): 3–8 weeks after Dose 1§
Previously vaccinated before 2024–2025 vaccine: • Receive 1 dose of 2024–2025 vaccine		
1 or more doses mRNA (Moderna or Pfizer-BioNTech) vaccine	1	**2024–2025 Dose 1** (Moderna, Novavax or Pfizer-BioNTech): At least 8 weeks after last dose
1 dose Novavax	1	**2024–2025 Dose 1** (Novavax): 3–8 weeks after last dose§¶
2 or more doses Novavax	1	**2024–2025 Dose 1** (Moderna, Novavax or Pfizer-BioNTech): At least 8 weeks after last dose

Table 5. Recommended COVID-19 Vaccination Schedule for Patients Who Are Not Moderately Severely Immunocompromised Ages 65 Years and Older

COVID-19 vaccination history before 2024–2025 vaccine*†	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine‡ and interval between doses
Unvaccinated: • Initiate vaccination with 2024–2025 vaccine		
Unvaccinated	2	**2024–2025 Dose 1** (Moderna or Pfizer-BioNTech): Day 0 **2024–2025 Dose 2** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 1
	OR	
	3	**2024–2025 Dose 1** (Novavax): Day 0 **2024–2025 Dose 2** (Novavax): 3–8 weeks after Dose 1§ **2024–2025 Dose 3** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 2
Previously vaccinated before 2024–2025 vaccine: • Receive 2 doses of 2024–2025 vaccine		
1 or more doses mRNA vaccine (Moderna or Pfizer-BioNTech)	2	**2024–2025 Dose 1** (Moderna, Novavax or Pfizer-BioNTech): At least 8 weeks after last dose **2024–2025 Dose 2** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1
1 dose Novavax	2	**2024–2025 Dose 1** (Novavax): 3–8 weeks after last dose§¶ **2024–2025 Dose 2** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1
2 or more doses Novavax	2	**2024–2025 Dose 1** (Moderna, Novavax or Pfizer-BioNTech): At least 8 weeks after last dose **2024–2025 Dose 2** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1

COVID-19 Vaccination for People Who Are Moderately or Severely Immunocompromised:

Unvaccinated:

- 4 doses (3-dose initial series 2024–25 Moderna at 0, 4 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]).
- 4 doses (3-dose initial series 2024–25 Pfizer-BioNTech at 0, 3 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]).
- 3 doses (2-dose initial series 2024–25 Novavax at 0, 3 weeks, followed by 1 dose Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]).
- Previously vaccinated with 1 dose of Moderna: 2-dose series of updated (2024–2025 Formula) Moderna at 0, 4 weeks (minimum interval between previous Moderna dose and dose 1: 4 weeks) followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months).
- Previously vaccinated with 2 doses of Moderna: Complete initial series with 1 dose 2024–25 Moderna at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months).
- Previously vaccinated with 1 dose of Pfizer- BioNTech: Complete initial series with 2 doses 2024–25 Pfizer-BioNTech at least 4 weeks apart (administer dose 1 3 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months).
- Previously vaccinated with 2 doses of Pfizer- BioNTech: Complete initial series with 1 dose 2024–25 Pfizer-BioNTech at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months).
- Previously vaccinated with 1 dose of Novavax: Complete initial series with 1 dose 2024–25 Novavax at least 3 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months).
- Completed the initial vaccination series before 2024–25 vaccine with:
    - 3 or more doses Moderna or 3 or more doses Pfizer-BioNTech: 2 doses 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose.

    - 2 or more doses Novavax: 2 doses 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose.
- Additional doses of the 2024-2025 COVID-19 vaccine for moderately or severely immunocompromised may be given based on shared clinical decision making and administered at least 2 months after the most recent dose.
- There is no preferential recommendation for the use of one COVID-19 vaccine over another when more than one recommended age-appropriate vaccine is available.
- The following table describes the recommended COVID-19 Vaccination Schedule for patients who are moderately or severely immunocompromised:

Table 6. Recommended COVID-19 Vaccination Schedule for Patients Who Are Moderately or Severely Immunocompromised

COVID-19 vaccination history before 2024–2025[#]	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine[§] and interval between doses
Unvaccinated: • Receive an initial series with 2024–2025 vaccine • Receive 1 dose of 2024–2025 vaccine 6 months (minimum interval 2 months) after completing initial series • May receive additional doses of 2024–2025 vaccine under shared clinical decision-making[¶]		
Unvaccinated	4	**2024–2025 Dose 1** (Moderna): Day 0 **2024–2025 Dose 2** (Moderna): 4 weeks after Dose 1 **2024–2025 Dose 3** (Moderna): At least 4 weeks after Dose 2 **2024–2025 Dose 4** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 3 **Additional doses** (Moderna, Novavax, or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]
	OR	
	3	**2024–2025 Dose 1** (Novavax): Day 0 **2024–2025 Dose 2** (Novavax): 3 weeks after Dose 1 **2024–2025 Dose 3** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 2 **Additional doses**: (Moderna, Novavax, or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]
	OR	
	4	**2024–2025 Dose 1** (Pfizer-BioNTech): Day 0 **2024–2025 Dose 2** (Pfizer-BioNTech): 3 weeks after Dose 1 **2024–2025 Dose 3** (Pfizer-BioNTech): At least 4 weeks after Dose 2 **2024–2025 Dose 4** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 3 **Additional doses** (Moderna, Novavax, or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]
Initiated but did not complete the initial series before 2024–2025 vaccine: • Complete the initial series with 2024–2025 vaccine • Receive 1 dose of 2024–2025 vaccine 6 months (minimum interval 2 months) after completing initial series • May receive additional doses of 2024–2025 vaccine under shared clinical decision-making[¶]		
1 dose Moderna	3	**2024–2025 Dose 1** (Moderna): 4 weeks after last dose **2024–2025 Dose 2** (Moderna): At least 4 weeks after 2024–2025 Dose 1 **2024–2025 Dose 3** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 2 **Additional doses** (Moderna, Novavax, or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]
2 doses Moderna	2	**2024–2025 Dose 1** (Moderna): At least 4 weeks after last dose **2024–2025 Dose 2** (Moderna, Novavax or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1 **Additional doses** (Moderna, Novavax or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]
1 dose Pfizer-BioNTech	3	**2024–2025 Dose 1** (Pfizer-BioNTech): 3 weeks after last dose **2024–2025 Dose 2** (Pfizer-BioNTech): At least 4 weeks after 2024–2025 Dose 1 **2024–2025 Dose 3** (Moderna, Novavax or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 2 **Additional doses** (Moderna, Novavax or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]
2 doses Pfizer-BioNTech	2	**2024–2025 Dose 1** (Pfizer-BioNTech): At least 4 weeks after last dose **2024–2025 Dose 2** (Moderna, Novavax or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1 **Additional doses** (Moderna, Novavax or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]
1 dose Novavax	2	**2024–2025 Dose 1** (Novavax): At least 3 weeks after last dose **2024–2025 Dose 2** (Moderna, Novavax or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1 **Additional doses** (Moderna, Novavax or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]

Completed the initial series before 2024–2025 vaccine: • Receive 2 doses of 2024–2025 vaccine spaced 6 months (minimum interval 2 months) apart • May receive additional doses of 2024–2025 vaccine under shared clinical decision-making[¶]		
3 or more doses Moderna or 3 or more doses Pfizer-BioNTech[#]	2	**2024–2025 Dose 1** (Moderna, Novavax or Pfizer-BioNTech): At least 8 weeks after last dose **2024–2025 Dose 2** (Moderna, Novavax or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1 **Additional doses** (Moderna, Novavax or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]
2 or more doses Novavax[#]	2	**2024–2025 Dose 1** (Moderna, Novavax or Pfizer-BioNTech): At least 8 weeks after last dose **2024–2025 Dose 2** (Moderna, Novavax or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1 **Additional doses** (Moderna, Novavax or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]

- Moderate and severe immunocompromising conditions and treatments include **but are not limited to**:
    - Active treatment for solid tumor and hematologic malignancies
    - Hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia)
    - Receipt of solid-organ transplant or an islet transplant and taking immunosuppressive therapy
    - Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppressive therapy)
    - Moderate or severe primary immunodeficiency (e.g., common variable immunodeficiency disease, severe combined immunodeficiency, DiGeorge syndrome, Wiskott-Aldrich syndrome)
    - Advanced HIV infection (people with HIV and CD4 cell counts less than 200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV) or untreated HIV infection.
    - Active treatment with high-dose corticosteroids (i.e., 20 mg or more of prednisone or equivalent per day when administered for 2 or more weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell-depleting agents)

- Factors to consider in assessing the general level of immune competence in a patient include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.
- Recipients of HCT or CAR-T-cell therapy who received 1 or more doses of COVID-19 vaccine prior to or during treatment should be revaccinated; Revaccination should start at least 3 months (12 weeks) after transplant or CAR-T-cell therapy and should follow the currently recommended schedule for people who are unvaccinated.
- Revaccination may also be considered for patients who received 1 or more doses of COVID-19 vaccine during treatment with B-cell-depleting therapies (e.g., rituximab, ocrelizumab) that were administered over a limited period (e.g., as part of a treatment regimen for certain malignancies) according to the currently recommended schedule.

  The suggested interval to start revaccination is about 6 months after completion of the B-cell-depleting therapy.

Considerations for Timing of COVID-19 Vaccination in Relation to Immunosuppressive Therapies:

- Administration of COVID-19 vaccines **should not be delayed** in patients taking immunosuppressive therapies.
- Whenever possible, COVID-19 vaccines should be administered **at least 2 weeks before initiation** or resumption of immunosuppressive therapies.
- For patients who receive B-cell-depleting therapies on a continuing basis, COVID-19 vaccines should be administered **approximately 4 weeks before** the next scheduled therapy.
- Timing of COVID-19 vaccination should take into consideration:
    - Current or planned immunosuppressive therapies
    - Optimization of both the patient's medical condition and anticipated response to vaccination
    - Individual benefits and risks

Age Transitions and Simultaneous Administration:

- CDC recommends that people receive the age-appropriate vaccine product and dosage based on their age on the day of vaccination.
- If a person moves to an older age group between vaccine doses, they should receive the vaccine product and dosage for the older age group.

Simultaneous Administration of COVID-19 Vaccines with other Vaccines:

- Coadministration is recommended for adults if there are no contraindications at the time of the healthcare visit.
- There is no required minimum interval between receiving a dose of any COVID-19 vaccine and an orthopoxvirus vaccine, either JYNNEOS or ACAM2000 vaccine (e.g., for mpox prevention), regardless of which vaccine is administered first.
- Use of JYNNEOS vaccine should be prioritized over ACAM2000 when co-administering a COVID-19 vaccine and an orthopoxvirus vaccine.
- People, particularly adolescent or young adult males, who are recommended to receive both vaccines might consider waiting 4 weeks between vaccines. This is because of the observed risk for myocarditis and pericarditis after receipt of ACAM2000 orthopoxvirus vaccine and COVID-19 vaccines, and the hypothetical risk for myocarditis and pericarditis after JYNNEOS vaccine. However, if a patient's risk for mpox or severe disease due to COVID-19 is increased, administration of mpox and COVID-19 vaccines should not be delayed.
- Nirsevimab: Simultaneous administration of COVID-19 vaccine and Nirsevimab (a long-acting monoclonal antibody indicated for certain infants and young children for prevention of RSV lower respiratory tract disease) is recommended.

Interchangeability of COVID-19 Vaccines:

Interchangeability of mRNA COVID-19 Vaccines:

- COVID-19 vaccine doses from the same manufacturer should be administered whenever recommended.
- In the following circumstances, an age-appropriate COVID-19 vaccine from a different manufacturer may be administered:
    - Same vaccine not available at the time of the clinic visit
    - Previous dose unknown
    - Person would otherwise not receive a recommended vaccine dose
    - Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication

m-RNA COVID-19 Vaccines:

- If mRNA vaccine doses are administered from different manufacturers because of a circumstance described above, a 3-dose schedule should be followed:

- *People ages 6 months and older who are moderately or severely immunocompromised:*
  - The second dose is administered 4 weeks after the first dose.
  - The third dose of either 2024–2025 Moderna vaccine or 2024–2025 Pfizer-BioNTech vaccine is administered as follows:
    - Ages 5 years and older: at least 4 weeks after the second dose

Novavax COVID-19 Vaccine:

- People aged 12 years and older who receive a first dose of Novavax COVID-19 Vaccine should complete the 2-dose initial vaccination series with Novavax vaccine.
- However, if more than 8 weeks have elapsed since receipt of the first dose of Novavax, any 2024–2025 COVID-19 vaccine (i.e., Moderna, Novavax, or Pfizer-BioNTech) may be administered under routine vaccination.

Precautions/Contraindications to COVID-19 Vaccination:

CDC considers the conditions listed below to be COVID-19 vaccination contraindications and precautions.

Table 7. Contraindications and Precautions to COVID-19 Vaccination

Medical Condition or History	Guidance	Recommended Action
History of a severe allergic reaction* (e.g., anaphylaxis†) after a previous dose or to a component of the COVID-19 vaccine‡	Contraindication	Do not vaccinate with the same COVID-19 vaccine type§ May administer the alternate COVID-19 vaccine type§
History of a diagnosed non-severe allergy* to a component of the COVID-19 vaccine‡	Precaution	May administer the alternate COVID-19 vaccine type§
History of a non-severe, immediate (onset less than 4 hours) allergic reaction* after administration of a previous dose of one COVID-19 vaccine type§	Precaution	

Moderate or severe acute illness, with or without fever	Precaution	Defer vaccination until the illness has improved.
History of MIS-C or MIS-A	Precaution	The benefits of COVID-19 vaccination for people with a history of MIS-C or MIS-A outweigh a theoretical risk of an MIS-like illness or the risk of myocarditis following COVID-19 vaccination for those who meet the following two recovery criteria: • Clinical recovery has been achieved, including return to baseline cardiac function; and • It has been at least 90 days after the diagnosis of MIS-C or MIS-A COVID-19 vaccination may also be considered for people who had MIS-C or MIS-A and do not meet both criteria, at the discretion of their clinical care team. Experts view clinical recovery, including return to baseline cardiac function, as an important factor when considering COVID-19 vaccination. Additional factors, such as the risk of severe COVID-19 due to age or certain medical conditions, may also be considered.
History of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine	Precaution	A subsequent dose of any COVID-19 vaccine should generally be avoided.

Abbreviations: MIS-C = multisystem inflammatory syndrome in children; MIS-A = multisystem inflammatory syndrome in adults

*Allergic reactions in Table 3 are defined as follows:

Severe allergic reactions include known or possible anaphylaxis, a progressive life-threatening reaction that typically includes urticaria (hives) but also with other symptoms such as wheezing, difficulty breathing, or low blood pressure; angioedema (visible swelling) affecting the airway (i.e., tongue, uvula, or larynx); diffuse rash which also involves mucosal surfaces (e.g., Stevens-Johnson Syndrome).

Non-severe allergic reactions include but are not limited to: urticaria beyond the injection site; angioedema involving lips, facial skin, or skin in other locations. NOTE: Any angioedema affecting the airway (i.e., tongue, uvula, or larynx) is considered a severe allergic reaction.

[†]Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines (estimated incidence: 5 per million doses of mRNA COVID-19 vaccines administered).

[‡]See package inserts and FDA EUA fact sheets for a full list of vaccine ingredients. mRNA COVID-19 vaccines contain polyethylene glycol (PEG).

[§]The mRNA COVID-19 vaccines (Moderna and Pfizer-BioNTech) are one type of COVID-19 vaccine, and the protein subunit vaccine (Novavax) is another type of COVID-19 vaccine.

Safety Considerations for COVID-19 Vaccines:

mRNA COVID-19 Vaccines:

The most frequent reported reactions, by age group can be summarized as follows:

People ages 12 years and older:

- Local: Pain at the injection site; less commonly, redness and swelling and axillary swelling/tenderness.
- Systemic: Fatigue, headache, myalgia, arthralgia, and chills; less commonly, fever and nausea/vomiting.

In all age groups, most symptoms were mild to moderate in severity, typically began 1–2 days after vaccination, and resolved after 1–3 days.

Novavax COVID-19 Vaccine:

In clinical trials of Novavax COVID-19 Vaccine, the most frequent reported vaccine reactions included:

- Local: Pain/tenderness at the injection site; less commonly, redness and swelling
- Systemic: Fatigue/malaise, headache, and myalgia; less commonly, arthralgia, nausea/vomiting, and fever.
- In addition, lymphadenopathy was also reported to occur after Novavax vaccination in the clinical trials.

Most symptoms were mild to moderate in severity, had onset 1-3 days after vaccination, and resolved within 1–3 days.

Overall, symptoms were more frequent in people ages 12–64 years compared to people ages 65 years and older and more frequent after dose 2 than dose 1 of the primary series.

COVID-19 Vaccination and SARS-CoV-2 Infection:

- COVID-19 vaccination is recommended for everyone aged 6 months and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection, including people with long COVID.
- People who recently had SARS-CoV-2 infection may consider delaying a COVID-19 vaccine dose by 3 months from symptom onset or positive test (if infection was asymptomatic).
- Studies have shown that increased time between infection and vaccination might result in an improved immune response to vaccination.
- A low risk of reinfection has generally been observed in the months following infection.
- Individual factors such as risk of COVID-19 severe disease and current indicators of community transmission should be taken into account when determining whether to delay getting a COVID-19 vaccination after infection.

Pregnancy, Lactation and Fertility Considerations:

- COVID-19 vaccination is recommended for people who are pregnant, trying to get pregnant now, or who might become pregnant in the future, and people who are breastfeeding.
- A growing body of evidence on the safety and effectiveness of COVID-19 vaccination indicates that the benefits of vaccination outweigh any potential risks of COVID-19 vaccination during pregnancy.
- Maternal vaccination has also been shown to be safe and effective and protects infants younger than age 6 months from severe COVID-19 and hospitalization.
- Side effects can occur after COVID-19 vaccination in pregnant people, similar to those among non-pregnant people.
- Acetaminophen can be offered as an option for pregnant people experiencing fever or other post-vaccination symptoms.

Hepatitis B Vaccination:

- **Age 19 through 59 years:** Complete a 2- or 3- or 4-dose series
    - 2-dose series only applies when 2 doses of Heplisav-B* are used at least 4 weeks apart

- 3-dose series Engerix-B, PreHevbrio*, or Recombivax HB at 0, 1, 6 months [minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 8 weeks / dose 1 to dose 3: 16 weeks])
- 3-dose series HepA-HepB (Twinrix at 0, 1, 6 months [minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 5 months])
- 4-dose series HepA-HepB (Twinrix) accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months

*Note: PreHevbrio is not recommended in pregnancy due to lack of safety data in pregnant people.

- **Age 60 years or older with known risk factors for hepatitis B virus infection** should complete a HepB vaccine series.
- **Age 60 years or older without known risk factors for hepatitis B virus infection** may complete a HepB vaccine series.
- **Any adult age 60 years of age or older** who requests HepB vaccination should receive a HepB vaccine series.
    - Risk factors for hepatitis B virus infection include:
        - Chronic liver disease (e.g., persons with hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level greater than twice upper limit of normal)
        - HIV infection
        - Sexual exposure risk (e.g., sex partners of hepatitis B surface antigen [HBsAg]-positive persons; sexually active persons not in mutually monogamous relationships; persons seeking evaluation or treatment for a sexually transmitted infection; men who have sex with men)
        - Current or recent injection drug use
        - Percutaneous or mucosal risk for exposure to blood (e.g., household contacts of HBsAg-positive persons; residents and staff of facilities for developmentally disabled persons; health care and public safety personnel with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids; persons on maintenance dialysis, including in-center or home hemodialysis and peritoneal dialysis, and persons who are predialysis; patients with diabetes*)
        - Incarceration

- Travel in countries with high or intermediate endemic hepatitis B

*__Age 60 years or older with diabetes:__ Based on shared clinical decision making, 2-, 3-, or 4-dose series as above.

- **Patients with Special Situations:**
    - **Patients on dialysis:** complete a 3- or 4-dose series
        - 3-dose series Recombivax HB at 0, 1, 6 months (note: use Dialysis Formulation 1 mL = 40 mcg)
        - 4-dose series Engerix-B at 0, 1, 2, and 6 months (note: use 2 mL dose instead of the normal adult dose of 1 mL)
    - **Age 20 years or older with an immunocompromising condition:**
        - complete a 2– or 3– or 4–dose series.
        - 3–dose series Recombivax HB at 0,1, 6 months(Note: Use Dialysis Formulation 1ml = 40 mcg)
        - 4 dose series Engerix–B at 0,1,2, and 6 months(Note: Use 2mL dose instead of the normal adult dose of 1mL)
        - 2 dose series Heplisav–B at 0, 1 months
        - 3 dose series PreHevbrio* at 0,1, 6 months
    - PreHevbrio is not recommended in pregnancy due to lack of safety data in pregnant persons.

<u>Human Papilloma Virus Vaccination:</u>

- **All persons up through age 26 years:** 2- or 3-dose series depending on age at initial vaccination or condition
    - **Age 9–14 years at initial vaccination and received 1 dose or 2 doses less than 5 months apart:** 1 additional dose
    - **Age 9 - 14 years at initial vaccination and received 2 doses at least 5 months apart:** HPV vaccination series complete, no additional dose needed
    - **Age 15 years or older at initial vaccination:** 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 12 weeks / dose 1 to dose 3: 5 months; repeat dose if administered too soon)
- No additional dose recommended when any HPV vaccine series of any valency has been completed using the recommended dosing intervals.

- **Adults aged 27–45 years**: Based on shared clinical decision-making, complete a 2-dose series (if initiated age 9-14 years) or 3-dose series (if initiated ≥15 years)
- As of 2018, the U.S. Food and Drug Administration approved a supplemental application for Gardasil 9 (Human Papillomavirus (HPV) 9-valent Vaccine, Recombinant) expanding the approved use of the vaccine to include women and men aged 27 through 45 years[28].
- As per the Harvard T.H. Chan School of Public Health, vaccinating adults older than age 26 against human papillomavirus (HPV) would provide limited health benefit, at a substantial cost[29].
- **Special Situations:**
    - **Immunocompromising conditions, including HIV infection:**
        - 3-dose series, even for those who initiate vaccination at age 9 through 14 years.
    - **Pregnancy:**
        - Pregnancy testing is not needed before vaccination; HPV vaccination is not recommended until after pregnancy; no intervention needed if inadvertently vaccinated while pregnant.

Influenza Vaccination:

- **Age 19 years or older:** 1 dose any influenza vaccine appropriate for age and health status annually.
- **Solid organ transplant recipients aged 19 through 64 years receiving immunosuppressive medications:** HD-IIV3 and aIIV3 are acceptable options. No preference over other age–appropriate IIV3 or RIV3.
- **Age 65 years or older:** Any one of HD-IIV3, RIV3, or aIIV3 is preferred. If none of these three vaccines is available, then any other age–appropriate influenza vaccine should be used.
- **Special Situations:**
    - Close contacts (e.g., caregivers, healthcare workers) of severely immunosuppressed persons who require a protected environment:
        - Those persons should not receive LAIV~~4~~3.
        - If LAIV3 is given, they should avoid contact with/caring for such immunosuppressed persons for 7 days after vaccination.
    - Persons with an egg allergy can receive any influenza vaccine (egg-based and non-egg based) appropriate for age and health status.

Measles, Mumps, and Rubella Vaccination:

- Should there be no evidence of immunity to measles, mumps, or rubella: 1 dose should be given.
- **Special Situations:**
    - Pregnancy with no evidence of immunity to rubella: MMR contraindicated during pregnancy; after pregnancy (before discharge from health care facility), 1 dose
    - Nonpregnant persons of childbearing age with no evidence of immunity to rubella: 1 dose
    - HIV infection with CD4 percentages ≥15% and CD4 count ≥200 cells/mm3 for at least 6 months and no evidence of immunity to measles, mumps, or rubella:
        - 2-dose series at least 4 weeks apart.
    - MMR is contraindicated for HIV infection with CD4 percentage <15% or CD4 count <200 cells/mm^3.
    - Severe immunocompromising conditions: MMR contraindicated
    - Students in postsecondary educational institutions, international travelers, and household or close, personal contacts of immunocompromised persons with no evidence of immunity to measles, mumps, or rubella: 2-dose series at least 4 weeks apart if previously did not receive any doses of MMR or 1 dose if previously received 1 dose MMR.
    - Health care personnel:
        - Born before 1957 with no evidence of immunity to measles, mumps, or rubella: Consider 2-dose series at least 4 weeks apart for protection against measles or mumps or 1 dose for protection against rubella.
        - Born in 1957 or later with no evidence of immunity to measles, mumps, or rubella: 2-dose series at least 4 weeks apart for protection against measles or mumps or at least 1 dose for protection against rubella.

Meningococcal Vaccination:

- **Special Situations for MenACWY:**
    - Anatomical or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:

        - 2-dose series MenACWY (Menveo, or MenQuadfi) at least 8 weeks apart and revaccinate every 5 years if risk remains.
    - Travel in countries with hyperendemic or epidemic meningococcal disease, or microbiologists routinely exposed to Neisseria meningitidis:
        - 1 dose MenACWY (Menveo, or MenQuadfi) and revaccinate every 5 years if risk remains.
    - First-year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits:
        - 1 dose MenACWY (Menveo, or MenQuadfi).
- **Shared Clinical Decision Making for MenB:**
    - Adolescents and young adults aged 16–23 years (age 16–18 years preferred) not at increased risk for meningococcal disease:
        - Bexsero or Trumenba (use same brand for all doses): 2–dose series at least 6 months apart (if dose 2 is administered earlier than 6 months, administer dose 3 at least 4 months after dose 2).
- **Special Situations for MenB:**
    - Anatomical or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use, or microbiologists routinely exposed to Neisseria meningitidis:
        - Bexsero or Trumenba (use same brand for all doses including booster doses): 3–dose primary series at 0, 1–2, 6 months (if dose 2 was administered at least 6 months after dose 1, dose 3 not needed; if dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3).
        - Booster doses: 1 booster dose one year after primary series and every 2–3 years if risk remains.
    - Pregnancy: Delay MenB until after pregnancy unless at increased risk and vaccination benefits outweigh potential risks.
    - MenB vaccines may be administered simultaneously with MenACWY vaccines if indicated, but at a different anatomic site, if feasible.
    - Adults may receive a single dose of Penbraya™ as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day.

- For adults not at increased risk, if Penbraya™ is used for dose 1 MenB, MenB-FHbp (Trumenba) should be administered for dose 2 MenB.
- For adults at increased risk of meningococcal disease, Penbraya™ may be used for additional MenACWY and MenB doses (including booster doses) if both would be given on the same clinic day **and** at least 6 months have elapsed since most recent Penbraya™ dose.

<u>Pneumococcal Vaccination:</u>

- **Age 50 years or older who have:**
    - Not previously received a dose of PCV13, PCV15, PCV20, or PCV21 or whose previous vaccination history is unknown: 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21.
        - If PCV15 is used, administer 1 dose PPSV23 at least 1 year after the PCV15 dose (may use minimum interval of 8 weeks for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak).
    - **Previously received only PCV7:**
        - follow the recommendation above.
    - **Previously received only PCV13:**
        - 1 dose PCV20 or 1 dose PCV21 at least 1 year after the last PCV13 dose.
    - **Previously received only PPSV23:**
        - 1 dose PCV15 **OR** 1 dose PCV20 **OR** 1 dose PCV21 at least 1 year after the PPSV23 dose.
    - **Previously received both PCV13 and PPSV23 but NO PPSV23 was received at age 65 years or older:**
    - 1 dose PCV20 **OR** 1 dose PCV21 at least 5 years after their last pneumococcal vaccine dose.
    - **Previously received both PCV13 and PPSV23, AND PPSV23 was received at age 65 years or older:**
        - Based on shared clinical decision-making, 1 dose of PCV20 **OR** 1 dose PCV21 at least 5 years after the last pneumococcal vaccine dose.

The CDC has provided the following link tackling Pneumococcal Vaccine Timing for Adults:

https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

- **Special Situations:**
    - Age 19-49 years with certain underlying medical conditions or other risk factors who have:
        - **Not previously received a PCV13, PCV15, PCV20 or PCV21 or whose previous vaccination history is unknown:**
            - 1 dose PCV15 **OR** 1 dose PCV20 OR 1 dose PCV21.
            - If PCV15 is used, this should be followed by a dose of PPSV23 given at least 1 year after the PCV15 dose. A minimum interval of 8 weeks between PCV15 and PPSV23 can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak.
        - **Previously received only PCV7:**
            - follow the recommendation above.
        - **Previously received only PCV13:**
            - 1 dose PCV20 **OR** 1 dose PCV21 at least 1 year after the PCV13 dose
        - **Previously received only PPSV23:**
            - 1 dose PCV15 **OR** 1 dose PCV20 **OR** 1 dose PCV21 at least 1 year after the PPSV23 dose. If PCV15 is used, it need not be followed by another dose of PPSV23.
        - **Previously received PCV13 and 1 dose of PPSV23:**
            - 1 dose PCV20 **OR** 1 dose PCV21 at least 5 years after their last pneumococcal vaccine dose
- Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease, or other hemoglobinopathies.
- Underlying medical conditions or other risk factors include alcoholism, chronic heart/liver/lung disease, chronic renal failure, cigarette smoking, cochlear implant, congenital or acquired asplenia, CSF leak, diabetes mellitus, generalized malignancy, HIV, Hodgkin disease, immunodeficiency, iatrogenic immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic

syndrome, solid organ transplants, or sickle cell disease, or other hemoglobinopathies.

Mpox Vaccination:

- Any person at risk for Mpox infection: 2-dose series, 28 days apart.
- Risk factors for Mpox infection include:
    - Persons who are gay, bisexual, and other MSM, transgender or nonbinary people who in the past 6 months have had:
        - A new diagnosis of at least 1 sexually transmitted disease
        - More than 1 sex partner
        - Sex at a commercial sex venue
        - Sex in association with a large public event in a geographic area where Mpox transmission is occurring
        - Persons who are sexual partners of the persons described above.
        - Persons who anticipate experiencing any of the situations described above.

  Healthcare personnel: Vaccination to protect against occupational risk in healthcare settings is not routinely recommended.

  Pregnancy: There is currently no ACIP recommendation for Jynneos use in pregnancy due to lack of safety data in pregnant persons. Pregnant persons with any risk factor described above may receive Jynneos.

Polio Vaccinations:

- **Vaccination**
    - Adults known or suspected to be unvaccinated or incompletely vaccinated:
        - Administer remaining doses (1, 2, or 3 IPV doses) to complete a 3-dose primary series.
        - Complete primary series consists of at least 3 doses of IPV or trivalent oral poliovirus vaccine (tOPV) in any combination.
- **Special Situations:**
    - **Adults at increased risk of exposure to poliovirus with:**
        - Evidence of completed polio vaccination series (i.e., at least 3 doses):
            - May administer one lifetime IPV booster.

Respiratory Syncytial Virus Vaccination:

- **Routine Vaccination:**
    - Pregnant at 32-36 weeks gestation from September through January in most of the continental United States: 1 dose RSV vaccine (Abrysvo™).
    - RSV vaccine is to be administered regardless of previous RSV infection.
    - Either maternal RSV vaccination or infant immunization with Nirsevimab (RSV monoclonal antibody) is recommended to prevent respiratory syncytial virus lower respiratory tract infection in infants.
    - All other pregnant persons: RSV vaccine not recommended
    - There is currently no ACIP recommendation for RSV vaccination in subsequent pregnancies. No data are available to inform whether additional doses are needed in later pregnancies.
    - Age 75 or older:
        - **Unvaccinated:** 1 dose (Arexvy or Abrysvo or mResvia). Additional doses not recommended.
        - **Previously vaccinated:** additional doses not recommended.
- **Special Situations:**
    - Age 60–74 years:
        - Unvaccinated and at increased risk of severe RSV disease: 1 dose (Arexvy or Abrysvo or mResvia). Additional doses not recommended.
        - Previously vaccinated: Additional doses not recommended. No data is available to inform whether additional doses are needed.
    - The following medical and other conditions increase the risk of severe RSV disease:
        - Chronic cardiovascular disease e.g., heart failure, coronary artery disease, congenital heart disease. Excludes isolated hypertension.
        - Chronic lung or respiratory disease e.g., chronic obstructive pulmonary disease, emphysema, asthma, interstitial lung disease, cystic fibrosis.
        - End stage renal disease or dependence on hemodialysis or other renal replacement therapy.
        - Diabetes mellitus complicated by chronic kidney disease, neuropathy, retinopathy, or other end–organ damage.

- Diabetes mellitus requiring treatment with insulin or sodium–glucose cotransporter 2 (SGLT2) inhibitor.
- Neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness e.g., post–stroke dysphagia, amyotrophic lateral sclerosis, muscular dystrophy. Excludes history of stroke without impaired airway clearance.
- Chronic liver disease e.g., cirrhosis
- Chronic hematologic conditions e.g., sickle cell disease, thalassemia
- Severe obesity (body mass index ≥ 40 kg/m2)
- Moderate or severe immune compromise
- Residence in a nursing home
- Other chronic medical conditions or risk factors that a health care provider determines would increase the risk of severe disease due to viral respiratory infection e.g., frailty, concern for presence of undiagnosed chronic medical conditions, residence in a remote or rural community where escalation of medical care is challenging.

Tetanus, diphtheria, and pertussis (Tdap) Vaccination:

- **Routine Vaccination:**
  - Completed primary series and received at least 1 dose Tdap at age 10 years or older: Td or Tdap every 10 years thereafter.
  - Completed primary series and did NOT receive Tdap at age 10 years or older: 1 dose Tdap, then Td or Tdap every 10 years thereafter.
  - Unvaccinated or incomplete primary vaccination series for tetanus, diphtheria, or pertussis: administer remaining doses (1, 2, or 3 doses) to complete 3–dose primary series. 1 dose Tdap followed by 1 dose Td or Tdap at least 4 weeks later, and a third dose of Td or Tdap 6–12 months later (Tdap is preferred as first dose and can be substituted for any Td dose), then Td or Tdap every 10 years thereafter.
- **Special Situations:**
  - **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36.

- **Wound Management:**
    - Persons with 3 or more doses of tetanus-toxoid-containing vaccine:
        - For clean and minor wounds, administer Tdap or Td if more than 10 years since last dose of tetanus-toxoid-containing vaccine.
        - For all other wounds, administer Tdap or Td if more than 5 years since last dose of tetanus-toxoid-containing vaccine.
    - Tdap is preferred for persons who have not previously received Tdap or whose Tdap history is unknown.
    - If a tetanus-toxoid-containing vaccine is indicated for a pregnant woman, use Tdap.

Varicella Vaccination

- **Routine Vaccination:**
    - **No evidence of immunity to varicella:** 2-dose series 4–8 weeks apart if previously did not receive varicella-containing vaccine (VAR or MMRV [measles-mumps-rubella-varicella vaccine] for children); if previously received 1 dose varicella-containing vaccine, 1 dose at least 4 weeks after first dose.
    - **Evidence of immunity:** U.S.-born before 1980 (except for pregnant persons and health care personnel), documentation of 2 doses varicella-containing vaccine at least 4 weeks apart, diagnosis or verification of history of varicella or herpes zoster by a health care provider, laboratory evidence of immunity or disease.
- **Special Situations:**
    - **Pregnancy with no evidence of immunity to varicella:** VAR contraindicated during pregnancy; after pregnancy (before discharge from health care facility), 1 dose if previously received 1 dose varicella-containing vaccine or dose 1 of 2-dose series (dose 2: 4–8 weeks later) if previously did not receive any varicella-containing vaccine, regardless of whether U.S.-born before 1980.
    - **Health care personnel with no evidence of immunity to varicella:** 1 dose if previously received 1 dose varicella-containing vaccine; 2-dose series 4–8 weeks apart if previously did not receive any varicella-containing vaccine, regardless of whether U.S.-born before 1980.
    - **HIV infection with CD4 percentages ≥15% and CD4 count ≥200 cells/mm3 with no evidence of immunity:**

        - Vaccination may be considered (2 doses 3 months apart).
        - VAR is contraindicated for HIV infection with CD4 percentage <15% or CD4 count <200 cells/mm3.
    - Severe immunocompromising conditions: VAR contraindicated.

Zoster Vaccination:

- **Age 50 years or older:**
    - 2-dose series recombinant zoster vaccine (RZV, Shingrix) 2–6 months apart (minimum interval: 4 weeks; repeat dose if administered too soon), regardless of previous herpes zoster or history of zoster vaccine live (ZVL, Zostavax) vaccination.
    - Serologic evidence of prior varicella is not necessary for zoster vaccination. However, if serologic evidence of varicella susceptibility becomes available, providers should follow ACIP guidelines for varicella vaccination first.
    - RZV is not indicated for the prevention of varicella, and there are limited data on the use of RZV in persons without a history of varicella or varicella vaccination.
- **Special Situations:**
    - **Pregnancy:**
        - Consider delaying RZV until after pregnancy.
    - **Immunocompromising conditions (including persons with HIV regardless of CD4 count):**
        - 2-dose series recombinant zoster vaccine (RZV, Shingrix) 2–6 months apart (minimum interval: 4 weeks; repeat dose if administered too soon).

Other recent recommendations as per the ACIP and CDC are summarized in the table below:

Table 8. ACIP 2025 Recommendations for Adult Immunization

Vaccines	Recommendations
Meningococcal Vaccines	Pfizer's MenABCWY vaccine may be used when both MenACWY and MenB are indicated at the same visit.* *Healthy individuals aged 16–23 years (routine schedule) when shared clinical decision-making favors administration of MenB vaccination, 2) individuals aged 10 years and older at increased risk of meningococcal

	disease (e.g., due to persistent complement deficiencies, complement inhibitor use, or functional or anatomic asplenia) due for both vaccines.
Mpox Vaccines	ACIP recommends vaccination[*] with the 2-dose[§] JYNNEOS vaccine series for persons aged 18 years and older at risk for Mpox[¶] [*]This is an interim recommendation that ACIP will revisit in 2-3 years [§]Dose 2 administered 28 days after dose 1 [¶]Persons at risk: • Gay, bisexual, and other men who have sex with men, transgender, or nonbinary people who in the past 6 months have had one of the following: o A new diagnosis of ≥1 sexually transmitted disease o More than one sex partner o Sex at a commercial sex venue o Sex in association with a large public event in a geographic area where Mpox transmission is occurring • Sexual partners of persons with the risks described in above • Persons who anticipate experiencing any of the above
Respiratory syncytial virus (RSV)	▪ Maternal Respiratory Syncytial Virus (RSV) vaccine (ABRYSVO™) is recommended for pregnant people during 32 through 36 weeks gestation, using seasonal administration, to prevent RSV lower respiratory tract infection in infants. ▪ ACIP recommends adults 75 years of age and older receive a single dose of RSV vaccine. ▪ ACIP recommends adults 60–74 years of age and older who are at increased risk of severe RSV disease receive a single dose of RSV vaccine.
COVID-19 (Moderna, Pfizer-BioNTech, Novavax)	ACIP recommends 2024-2025 COVID-19 vaccines as authorized or approved by FDA in persons ≥ 6 months of age. ACIP recommends persons ≥ 65 years of age should receive an additional dose of 2023–2024 Formula COVID-19 vaccine.
Poliovirus (IPV)	▪ Adults who are known or suspected to be unvaccinated or incompletely vaccinated against polio should complete a primary vaccination series with inactivated polio vaccine (IPV).

	▪ Adults who have received a primary series of trivalent oral polio vaccine (tOPV) or IPV in any combination and who are at increased risk of poliovirus exposure may receive another dose of IPV. ▪ Available data do not indicate the need for more than a single lifetime booster dose with IPV for adults.
Influenza (IIV4, ccIV4, RIV4, LAIV4)	▪ All persons aged ≥ 6 months with egg allergy should receive influenza vaccine. Any influenza vaccine (egg based or non-egg based) that is otherwise appropriate for the recipient's age and health status can be used. ▪ ACIP recommends high-dose inactivated (HD-IIV3) and adjuvanted inactivated (aIIV3) influenza vaccines as acceptable options for influenza vaccination of solid organ transplant recipients aged 18 through 64 years who are on immunosuppressive medication regimens, without a preference over other age-appropriate IIV3s or RIV3.
Pneumococcal Conjugate Vaccine	ACIP recommends PCV21 as an option for adults aged ≥ 19 years who currently have a recommendation to receive a dose of PCV.

Contraindications and Precautions:

The following table was adapted from the 2025 ACIP Clinical Guideline:

Table 9. Vaccines Contraindications and Precautions

Vaccine	Contraindicated or Not Recommended	Precautions
COVID-19 mRNA vaccines [Pfizer-BioNTech, Moderna]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine.	• Diagnosed non-severe allergy (e.g., urticaria beyond the injection site) to a component of an mRNA COVID-19 vaccine; or non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a

		previous dose of an mRNA COVID-19 vaccine • Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine • Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A) • Moderate or severe acute illness, with or without fever
COVID-19 protein subunit vaccine [Novavax]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a Novavax COVID-19 vaccine.	• Diagnosed non-severe allergy (e.g., urticaria beyond the injection site) to a component of Novavax COVID-19 vaccine; or non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of a Novavax COVID-19 vaccine • Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine • Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A)

		• Moderate or severe acute illness, with or without fever
Influenza, egg-based, inactivated injectable (IIV3)	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component (excluding egg)	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Moderate or severe acute illness with or without fever
Influenza, cell culture-based inactivated injectable [(ccIIV3), Flucelvax®]	• Severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency, or to any component of ccIIV3	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, RIV, or LAIV of any valency. If using ccIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, recombinant injectable [(RIV3), Flublok®]	• Severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency, or to any component of RIV3	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of

		any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, ccIIV, or LAIV of any valency. If using RIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, live attenuated [LAIV3, Flumist®]	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component (excluding egg) • Anatomic or functional asplenia • Immunocompromised due to any cause including, but not limited to, medications and HIV infection • Close contacts or caregivers of severely immunosuppressed	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Asthma in persons aged 5 years or older • Persons with underlying medical conditions (other than those listed under contraindications) that might predispose to complications after wild-type influenza virus infection [e.g., chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus)]

	persons who require a protected environment • Pregnancy • Cochlear implant • Active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, ear, or any other cranial CSF leak • Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days.	• Moderate or severe acute illness with or without fever
Haemophilus influenzae type b (Hib)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness with or without fever
Hepatitis A (HepA)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component including neomycin	• Moderate or severe acute illness with or without fever
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component including yeast • Pregnancy: PreHevbrio is not recommended due to lack of safety data in pregnant persons. Use other hepatitis B	• Moderate or severe acute illness with or without fever

	vaccines if HepB is indicated	
Hepatitis A-Hepatitis B vaccine [HepA-HepB, (Twinrix®)]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component including neomycin and yeast	• Moderate or severe acute illness with or without fever
Human papillomavirus (HPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Pregnancy: HPV vaccination not recommended	• Moderate or severe acute illness with or without fever
Measles, mumps, rubella (MMR)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • History of thrombocytopenia or thrombocytopenic purpura • Need for tuberculin skin testing or interferon-gamma release assay (IGRA) testing • Moderate or severe acute illness with or without fever

Meningococcal ACWY (MenACWY) [MenACWY-CRM (Menveo®); MenACWY-TT (MenQuadfi®)]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • For MenACWY-CRM only: severe allergic reaction to any diphtheria toxoid–or CRM197–containing vaccine • For MenACWY-TT only: severe allergic reaction to a tetanus toxoid-containing vaccine	• Moderate or severe acute illness with or without fever
Meningococcal B (MenB) [MenB-4C (Bexsero®); MenB-FHbp (Trumenba®)]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Pregnancy • For MenB-4C only: Latex sensitivity • Moderate or severe acute illness with or without fever
Meningococcal ABCWY (MenACWY-TT/MenB-FHbp) [Penbraya]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Severe allergic reaction to a tetanus toxoid-containing vaccine	• Moderate or severe acute illness, with or without fever
Mpox [Jynneos]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness, with or without fever
Pneumococcal conjugate (PCV15, PCV20, PCV21)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Severe allergic reaction (e.g., anaphylaxis) to any diphtheria-toxoid–	• Moderate or severe acute illness with or without fever

	containing vaccine or to its vaccine component	
Pneumococcal polysaccharide (PPSV23)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness with or without fever
Poliovirus vaccine, inactivated (IPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Pregnancy • Moderate or severe acute illness with or without fever
Respiratory syncytial virus vaccine (RSV)	• Severe allergic reaction (e.g., anaphylaxis) to a vaccine component	• Moderate or severe acute illness with or without fever
Tetanus, diphtheria, and acellular pertussis (Tdap) **Tetanus, diphtheria (Td)**	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus-toxoid–containing vaccine
	• For Tdap only: Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures), not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP, DTaP, or Tdap	• History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid–containing or tetanus-toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid–containing vaccine • Moderate or severe acute illness with or without fever • For Tdap only: Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a

		treatment regimen has been established and the condition has stabilized
Varicella (VAR)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vaccination) • Use of aspirin or aspirin-containing products • Moderate or severe acute illness with or without fever
Zoster recombinant vaccine (RZV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness with or without fever • Current herpes zoster infection

1.1.2 UK Immunization Schedule [2025]

The following guidelines do not provide a specified grade of evidence or level of recommendation.

*Please refer to **Section 1.2** of the CHI Adult Immunization Report Version 2.*

The UK Health Security Agency has issued a 2025 complete routine immunization schedule updated in January of 2025; the recommendations are detailed below[30]:

Table 10. Adult Routine Immunization Schedule as Per GOV.UK

When	Diseases Protected Against	Vaccine Given	Trade Name	Usual Site
65 years old	Pneumococcal (23 serotypes)	Pneumococcal polysaccharide vaccine (PPV23)	Pneumovax 23	Upper arm
65 years of age and older	Influenza (each year from September)	Inactivated influenza vaccine	Multiple	Upper arm
65 from September 2023	Shingles	Shingles vaccine	Shingrix	Upper arm
70 to 79 years of age (plus eligible age groups and severely immunosuppressed)	Shingles	Shingles vaccine	Zostavax (or Shingrix if Zostavax contraindicated)	Upper arm
75 years old	Respiratory syncytial virus (RSV)	RSV vaccine	Abrysvo	Upper arm

The following tables provides proposed selective immunization programs:

Table 11. Selective Immunization Programs for Adults

Target Group	Age And Schedule	Disease	Vaccines Required
Pregnant Women	At any stage of pregnancy during flu season	Influenza	Inactivated flu vaccine
	From 16 weeks gestation	Pertussis	Tdap (ADACEL)
	From 28 weeks gestation	RSV	RSV vaccine (Abrysvo)

The following table summarizes the additional vaccines required for individuals suffering from underlying conditions:

Table 12. Additional Vaccines for Individuals with Underlying Medical Conditions

Medical Condition	Diseases Protected Against	Vaccines Required
Asplenia or splenic dysfunction (including due to sickle cell and celiac disease)	Meningococcal groups A, B, C, W and Y	MenACWY MenB
	Pneumococcal	PCV13 (up to 10 years of age) PPV23 (from 2 years of age)
	Influenza	Annual flu vaccine
Cochlear implants	Pneumococcal	PCV13 (up to 10 years of age) PPV23 (from 2 years of age)
Chronic respiratory and heart conditions (such as severe asthma, chronic pulmonary disease, and heart failure)	Pneumococcal	PCV13 (up to 10 years of age) PPV23 (from 2 years of age)
	Influenza	Annual flu vaccine
Chronic neurological conditions (such as Parkinson's or motor neuron disease, or learning disability)	Pneumococcal (only if the individual is also at increased risk of aspiration)	PCV13 (up to 10 years of age) PPV23 (from 2 years of age)
	Influenza	Annual flu vaccine
Diabetes	Pneumococcal	PCV13 (up to 10 years of age) PPV23 (from 2 years of age)
	Influenza	Annual flu vaccine
Chronic kidney disease (CKD) (including hemodialysis)	Pneumococcal (stage 4 and 5 CKD)	PCV13 (up to 10 years of age) PPV23 (from 2 years of age)
	Influenza (stage 3, 4 and 5 CKD)	Annual flu vaccine

	Hepatitis B (stage 4 and 5 CKD)	Hepatitis B
Chronic liver conditions	Pneumococcal	PCV13 (up to 10 years of age) PPV23 (from 2 years of age)
	Influenza	Annual flu vaccine
	Hepatitis A	Hepatitis A
	Hepatitis B	Hepatitis B
Hemophilia	Hepatitis A	Hepatitis A
	Hepatitis B	Hepatitis B
Immunosuppression due to disease or treatment	Pneumococcal	PCV13 (up to 10 years of age) PPV23 (from 2 years of age)
	Shingles vaccine	Shingrix – over 50 years of age
	Influenza	Annual flu vaccine
Complement disorders (including those receiving complement inhibitor therapy)	Meningococcal groups A, B, C, W and Y	MenACWY MenB
	Pneumococcal	PCV13 (up to 10 years of age) PPV23 (from 2 years of age)
	Influenza	Annual flu vaccine

1.2 Additional Guidelines

This section includes the added guidelines to the previous CHI Adult Immunization report, along with their recommendations.

Table 13. List of Additional Guidelines

Additional Guidelines
KSA: Saudi Clinical Preventive Guideline [2023]
North American: - WHO Routine Immunization Schedule [2024]

International:

- Australian National Immunization Program Schedule [2024]
- Canada's Improving Adult Immunization [2025]

1.2.1 Saudi Clinical Preventive Guideline [2023]

The General directorate of Health Centers Affairs and Health Programs nominated a team to develop Saudi Clinical Preventive Guideline (SCP) program to be implemented in Primary Health Care centers; the following grades of recommendation and levels of evidence were opted:

Table 14. SCPG Grade of Recommendation/Level of Evidence

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

	benefits and harms cannot be determined.	

- The public health authority (PHA) recommends routine vaccination to prevent 17 vaccine-preventable diseases that occur in infants, children, adolescents and adults.
- Immunization processes stimulate the body's own immune system to protect the person against subsequent infection or disease.
- The following table summarizes vaccine recommendations for adults aged 18 years and older along with their timing and indication:

Timing/Indication:

1. **Influenza Vaccine:** To be dosed annually.
2. **Tdap or Td Vaccine for Adults:** Dose Tdap then Td booster every 10 years.
3. **Tdap or Td Vaccine for Pregnant women** (for each pregnancy between 27 & 36 weeks).
4. **MMR Vaccine:** For unvaccinated individuals, premarital and post-natal women if no evidence of immunity or prior disease (1 or 2 doses depend on indication).
5. **Varicella Vaccine:** If no evidence of immunity or prior disease (2 doses 8 weeks apart).
6. **Herpes Zoster Vaccine:** 2 doses 2-6 months apart for adults aged 50 years or older.
7. **HPV Vaccine:** 3 doses (0, 1-2, and 6 months) from the first dose catch up immunization for females aged 15-26 years.
8. **PPSV23 Vaccine:** 1 dose adults aged 65 years or older (1 year after PCV 13 dose) from the first dose.
9. **PCV Vaccine:** 1 dose adults with comorbid/immunocompromised conditions and adults aged 65 years or older.
10. **Hepatitis B Vaccine:** 3 doses (0, 1 month, and 6 months) if no previous immunization or no evidence of immunity.
11. **MCV4 Vaccine:** 1 dose depending on indication, then booster every 5 years if risk remains.

1.2.2 WHO Routine Immunization Schedule [2024]

The following guidelines do not provide a specified grade of evidence or level of recommendation.

The World Health Organization has issued updated position papers on the different recommended vaccinations; these position papers are summarized into tables; the recommendations are detailed below[31]:

Table 15. Recommendations for Routine Immunization

Antigen		Children (see Table 2 for details)		Adolescents	Adults	Considerations (see footnotes for details)
Recommendations for all immunization programmes						
BCG[1]		1 dose				Birth dose and HIV; Universal vs selective vaccination; Co-administration; Vaccination of older age groups; Pregnancy
Hepatitis B[2]		3-4-doses (see footnote for schedule options)		3 doses (for high-risk groups if not previously immunized) (see footnote)		Birth dose Premature and low birth weight Co-administration and combination vaccine Definition high-risk
Polio[3]		3-5 doses (at least 2 doses of IPV) with DTPCV				bOPV birth dose; Type of vaccine; Fractional dose IPV; Transmission and importation risk; Local epidemiology, programmatic implications and feasibility for "early" option
DTP-containing vaccine (DTPCV)[4]		3 doses	2 boosters 12-23 months (DTPCV) and 4-7 years (Td/DT containing vaccine, see footnote)	1 booster 9-15 yrs (Td)		Delayed/interrupted schedule Combination vaccine Maternal immunization
***Haemophilus influenzae* type b**[5]	**Option 1**	3 doses, with DTPCV				Single dose if > 12 months of age Not recommended for children > 5 yrs old Delayed/interrupted schedule Co-administration and combination vaccine
	Option 2	2 or 3 doses, with booster at least 6 months after last dose				
Pneumococcal (Conjugate)[6]	**Option 1**	3 primary doses (3p+0) with DTPCV				Schedule options (3p+0 vs 2p+1) Vaccine options HIV+ and preterm neonate booster Vaccination in older adults
	Option 2	2 primary doses plus booster dose at 9-18 mos of age (2p+1) with DTPCV				
Rotavirus[7]		2-3 doses depending on product with DTPCV				Not recommended if > 24 months old
Measles[8]		2 doses				Co-administration live vaccines; Combination vaccine; HIV early vaccination; Pregnancy
Rubella[9]		1 dose (see footnote)		1 dose (adolescent girls and women of reproductive age if not previously vaccinated; see footnote)		Achieve and sustain 80% coverage Combination vaccine and Co-administration Pregnancy
HPV[10]				1-2 doses (females)		Target 9-14 year old girls; Off-label 1 dose schedule; MACs with intro; Pregnancy; HIV and immunocompromised

Antigen		Children (see Table 2 for details)	Adolescents	Adults	Considerations (see footnotes for details)
Recommendations for certain regions					
Japanese Encephalitis[11]		*Inactivated Vero cell-derived vaccine:* generally 2 doses *Live attenuated vaccine:* 1 dose *Live recombinant vaccine:* 1 dose			Co-administration live vaccines; Vaccine options and manufacturer's recommendations; Pregnancy; Immunocompromised
Yellow Fever[12]		1 dose, with measles containing vaccine			Co-administration live vaccines
Tick-Borne Encephalitis[13]		3 doses (> 1 yr FSME-Immun and Encepur; > 3 yrs TBE-Moscow and EnceVir) with at least 1 booster dose (every 3 years for TBE-Moscow and EnceVir)			Definition of high-risk Vaccine options Timing of booster
Recommendations for some high-risk populations					
Typhoid[14]		*Typhoid conjugate vaccine (Typbar-TCV®):* 1 dose; *Vi polysaccharide(ViPS):* 1 dose; *Ty21a live oral vaccine:* 3-4 doses (see footnote); *Revaccination for ViPS & Ty21a; every 3-7 years*			Definition of high-risk Vaccine options
Cholera[15]		*Dukoral (WC-rBS):* 3 doses ≥ 2-5 yrs, booster every 6 months; 2 doses adults/children ≥ 6 yrs, booster every 2nd year; *Shanchol, Euvchol & mORCVAX:* 2 doses ≥1 yrs, booster dose after 2 yrs			Minimum age Definition of high-risk
Meningococcal[16]	**MenA conjugate**	1 dose 9-18 months (5µg)			2 doses if < 9 months with 8 week interval
	MenC conjugate	2 doses (2-11 months) with booster 1 year after 1 dose (≥12 months)			Definition of high-risk; Vaccine options
	Quadrivalent conjugate	2 doses (9-23 months) 1 dose (≥2 years)			
Hepatitis A[17]		Inactivated: 1 or 2 doses ≥ 12 months Live attenuated: 1 dose >18 months of age		Inactivated: 2 doses if > 40 years of age	Level of endemicity; Vaccine options; Definition of high risk groups
Rabies[18]		2 doses			PrEP vs PEP; definition of high risk; booster
Dengue (CYD-TDV)[19]		3 doses 9-45 years of age			Minimize risk of vaccine among seronegative individuals by pre-vaccination screening;Pregnancy & lactation
Malaria (RTS,S)[20]		4 doses			Moderate to high malaria transmission; Strategy for highly seasonal transmission, see notes
Recommendations for immunization programmes with certain characteristics					
Mumps[21]		2 doses with measles and rubella containing vaccine			High coverage with MR vaccine Combination vaccines
Seasonal influenza (inactivated tri-and quadri-valent)[22]		First vaccine use: 2 doses Revaccinate annually: 1 dose only (see footnote)	1 dose ≥ 9 years of age	Revaccinate annually	Priority risk groups
Varicella[23]		1 - 2 doses	2 doses		Achieve & sustain ≥ 80% coverage Pregnancy Co-administration with other live vaccines

BCG:

- BCG vaccination is recommended for unvaccinated TST- or IGRA-negative older children, adolescents and **adults** from settings with high incidence of TB and/or high leprosy burden, those moving from low to high TB incidence/ leprosy burden settings and persons at risk of occupational exposure in low and high TB incidence areas (e.g. health-care workers, laboratory workers, medical students, prison workers, other individuals with occupational exposure).
- BCG vaccination is not recommended during pregnancy.
- If HIV-infected individuals, including children, are receiving ART, are clinically well and immunologically stable (CD4% >25% for children aged <5 years or CD4 count ≥200 if aged >5 years) they can be vaccinated with BCG.

Hepatitis B:

- For catch-up of unvaccinated individuals, priority should be given to younger age groups since the risk of chronic infection is highest in these cohorts.
- Unvaccinated individuals should be vaccinated with a 0, 1, 6 month schedule.

- Vaccination of groups at highest risk of acquiring HBV is recommended.

  These include patients who frequently require blood or blood products, dialysis patients, diabetes patients, recipients of solid organ transplantation, person with chronic liver disease including those with Hepatitis C, person with HIV infection, men who have sex with men, persons with multiple sexual partners, as well as health care workers and others who may be exposed to blood, blood products or other potentially infectious body fluids during their work.

DTP-containing vaccines (Diphtheria, Tetanus and Pertussis):

- If tetanus vaccination is started during adolescence or adulthood, a total of only 5 appropriately spaced doses are required to obtain lifelong protection.
- Pregnant women and their newborn infants are protected from birth-associated tetanus if the mother received either 6 TTCV doses during childhood or 5 doses if first vaccinated during adolescence/adulthood (documented by card, immunization registry and/or history) before the time of reproductive age.
- Vaccination history should be verified in order to determine whether a dose of TTCV is needed in the current pregnancy.
- Vaccinating pregnant women and household contacts: Vaccination of pregnant women is likely to be the most cost-effective additional strategy for preventing disease in infants too young to be vaccinated and appears to be more effective and favorable than cocooning.
- National programs may consider the vaccination of pregnant women with 1 dose of Tdap (in the 2nd or 3rd trimester and preferably at least 15 days before the end of pregnancy) as a strategy additional to routine primary infant pertussis vaccination in countries or settings with high or increasing infant morbidity/mortality from pertussis.
- Health-care workers should be prioritized as a group to receive pertussis vaccine.

Rubella:

- Rubella vaccination should be avoided in pregnancy because of a theoretical risk of teratogenic outcomes.
- Women planning a pregnancy are advised to avoid pregnancy for 1 month after rubella vaccination.
- WHO recommends that people who receive blood products wait at least 3 months before vaccination with RCV, and, if possible, avoid administration of blood products for 2 weeks after vaccination.

Human Papillomavirus:

- Vaccination of secondary target populations, e.g. females aged ≥15 years, boys, older males or MSM, is recommended only if this is feasible and affordable, and does not divert resources from vaccination of the primary target population or effective cervical cancer screening programs.
- The current evidence supports the recommendation that a 2-dose schedule be used in the primary target group from 9 years of age and for all older age groups for which HPV vaccines are licensed.
- The minimum interval between first and second dose is 6 months.
- A 12-month schedule results in higher GMTs and is suggested for programmatic and efficiency reasons.
- There is no maximum recommended interval between doses and longer intervals – up to 3 or 5 years – can be considered if useful from a program perspective.
- Alternative single-dose schedule: As an off-label option, a single-dose schedule can be used in girls and boys aged 9–20 years. Current evidence suggests that a single dose has comparable efficacy and duration of protection as a 2-dose schedule and may offer program advantages, be more efficient and affordable, and contribute to improved coverage.
- Individuals known to be immunocompromised or HIV-infected (regardless of age or antiretroviral therapy status) should receive at least two HPV vaccine doses (minimum 6 months interval) and, where possible, three doses.
- HPV vaccines can be co-administered with other non-live and live vaccines using separate syringes and different injection sites.
- As a precaution HPV vaccine is not recommended in pregnancy.
- If pregnancy occurs following the first dose of vaccination, the subsequent dose should be delayed until after the pregnancy.
- Termination of pregnancy is not indicated if vaccination was carried out inadvertently during pregnancy.
- Breastfeeding is not a contraindication for HPV vaccination.

Recommendations for High-Risk Individuals:

Typhoid:

- Among the available typhoid vaccines, TCV is preferred at all ages in view of its improved immunological properties and expected duration of protection.

- TCV - for infants and children from 6 months of age and in adults up to 45 years.
- Typhoid vaccination is recommended in response to confirmed outbreaks of typhoid fever and may be considered in humanitarian emergency settings depending on the risk assessment in the local setting.
- Countries may consider the routine use of ViPS vaccine in individuals 2 years and older, and Ty21a vaccine for individuals more than 6 years of age.
- ViPS – single dose from 2 years of age.
- Ty21a – 3-doses to be administered orally every second day from 6 years of age.
- Revaccination is recommended every 3 years for ViPS, and every 3-7 years for Ty21a.
- The potential need for revaccination with TCV is currently unclear.
- Use of the live attenuated Ty21a vaccine during pregnancy should be avoided because of theoretical safety concerns about potential adverse effects.

Cholera:

- WC vaccines (Shanchol, Euvchol, and mORCVAX) 2 doses should be given 14 days apart to individuals ≥ 1 year of age.
- For WC-rBS vaccine (Dukoral), 2 doses should be given to adults, with an interval of 1-6 weeks between doses.
- Revaccination is recommended where there is continued risk of V. cholerae infection.
- For WC vaccines revaccination is recommended after 3 years.
- For WC-rBS vaccine: For those aged ≥ 6 years of age, if less than 2 years have passed, 1 dose for revaccination. If more than 2 years have passed, the primary series of 2 doses should be repeated.
- In cholera-endemic countries, vaccination of the entire population (throughout a country regardless of risk) is usually not warranted.
- During humanitarian emergencies with a risk of cholera, but without a current cholera outbreak, vaccination with OCV should be considered as an additional preparedness measure for outbreak prevention, depending on the local infrastructure (capacity to organize a vaccination campaign).
- Pregnant and lactating women and HIV infected individuals should be included in OCV campaigns since there is a high potential benefit and minimal risks.

Meningococcal:

- Conjugate vaccines are preferred over polysaccharide vaccines due to their potential for herd protection and their increased immunogenicity.
- Both conjugate and polysaccharide vaccines are efficacious and safe when used in pregnant women.
- For monovalent MenC conjugate vaccine one single intramuscular dose is recommended for children aged ≥12 months, teenagers and adults.
- Quadrivalent conjugate vaccines (A,C,W135,Y-D and A,C,W135,Y-CRM) should be administered as one single intramuscular dose to individuals ≥ 2 years.
- Meningococcal polysaccharide vaccines can be used for those ≥ 2 years of age to control outbreaks in countries where limited economic resources or insufficient supply restrict the use of meningococcal conjugate vaccines.
- Polysaccharide vaccines should be administered to individuals ≥ 2 years old as one single dose. One booster 3-5 years after the primary dose may be given to persons considered to have a continued high risk of exposure, including some health workers.

Hepatitis A:

- WHO recommends that vaccination against hepatitis A virus be introduced into national immunization schedules for individuals aged ≥12 months, if indicated on the basis of:
    i) an increasing trend over time of acute hepatitis A disease, including severe disease, among older children, adolescents or adults;
    ii) changes in the endemicity from high to intermediate;
    iii) considerations of cost– effectiveness.
- In highly endemic countries, most individuals are asymptomatically infected with HAV in childhood, which prevents clinical hepatitis A in adolescence and adulthood.

  In these countries, large-scale hepatitis A vaccination programs are not routinely recommended, because they carry a risk of a paradoxical increase in disease incidence in unvaccinated people.
- Groups at higher risk of hepatitis A should be vaccinated:

  Such groups include travelers from low-endemic countries to areas of intermediate or high endemicity, men who have sex with men, at-risk occupational groups (such as sewage workers or laboratory personnel handling hepatitis A virus specimens), people who inject drugs, people who experience homelessness, migrants, refugees, incarcerated persons; and

patients with chronic liver disease or people living with HIV, particularly in countries with low and very low endemicity.

- **Inactivated vaccine:** For adults aged >40 years, vaccination with inactivated vaccines using the 2-dose schedule is preferred since there is insufficient evidence on the immunogenicity and long-term protection from a single dose in this age group.
- Inactivated hepatitis A vaccines produced by different manufacturers, including combined hepatitis A vaccines, are interchangeable.
- For immunocompromised individuals, a 2-dose schedule of inactivated vaccine is recommended.
- Inactivated hepatitis A vaccines should also be considered for use in pregnant women at risk of HAV infection.
- **Live attenuated vaccine:** Live attenuated vaccines are licensed for individuals aged ≥18 months and are administered as a single subcutaneous dose.

Rabies:

- There are two main immunization strategies for the prevention of human rabies:
    - PEP which includes extensive and thorough wound washing at the RABV-exposure site, together with RIG administration if indicated, and the administration of a course of several doses of rabies vaccine.
    - PrEP which is the administration of several doses of rabies vaccine before exposure to RABV.

      PrEP is recommended for individuals at high risk of RABV exposure. These include sub-populations in highly endemic settings with limited access to timely and adequate PEP, individuals at occupational risk, and travelers who may be at risk of exposure.
- For both PEP and PrEP, vaccines can be administered by either the ID or IM route:
    - One ID dose is 0.1 mL of vaccine; one IM dose is 0.5 mL or 1.0 mL depending on the product.
- The following table details the different categories of Rabies[32]:

Table 16. Rabies Categories

Category	Characteristics
Category I	Touching or feeding animals, animal licks on intact skin (no exposure)
Category II	Nibbling of uncovered skin, minor scratches, or abrasions without bleeding (exposure)
Category III	Single or multiple transdermal bites or scratches, contamination of mucous membrane or broken skin with saliva from animal licks, exposures due to direct contact with bats (severe exposure).

- For category I exposures, no PEP is required.
- For category II, immediate vaccination is recommended.
- For category III, immediate vaccination is recommended, and administration of RIG, if indicated.
- PrEP schedule: 2-site ID vaccine administered on days 0 and 7.
- If IM administration is used, WHO recommends a 1-site IM vaccine administration on days 0 and 7.
- If any doses are delayed, vaccination should be resumed, not restarted.
- A change in the route of administration or in vaccine product during a PEP or PrEP course is acceptable if such a change is unavoidable.
- Professionals who are at continual or frequent risk of exposure through their activities should have regular serological monitoring.

  If VNA levels fall to < 0.5 IU/mL, a 1-site ID or a 1-site IM PrEP booster vaccination is recommended.

  If serological testing is not available for those at continual or frequent occupational risk, a periodic 1-dose (ID or IM) PrEP booster vaccination can be considered based on the assessment of relative risk.

Dengue:

- For countries considering vaccination as part of their dengue control program, pre-vaccination screening is the recommended strategy.
- If pre-vaccination screening is not feasible, vaccination without individual screening could be considered in areas with recent documentation of seroprevalence rates of at least 80% by age 9 years.
- CYD-TDV is recommended as a 3-dose series given 6 months apart.

- Should a vaccine dose be delayed for any reason, it is not necessary to restart the course and the next dose in the series should be administered as soon as possible.
- CYD-TDV is not recommended in pregnant and lactating women because insufficient data are available on its use in pregnancy.
- Due to lack of data, CYD-TDV is contraindicated in immunocompromised individuals.

Recommendations for Immunization Programs with Certain Characteristics:

Seasonal Influenza (Inactivated Tri-and Quadri-valent):

- For countries considering the initiation or expansion of programs for seasonal influenza vaccination, WHO recommends that the following target groups should be considered for vaccination (not in order of priority): health workers, individuals with comorbidities and underlying conditions, older adults and pregnant women.
- Other groups to be considered for vaccination include people at high risk of severe influenza living in congregate-living settings, such as prisons, refugee camps and group homes.
- A single dose is appropriate for those ≥ 9 years of age and healthy adults.
- Those who have previously been vaccinated at least once should subsequently receive 1 annual dose, as should children and adolescents aged 9 years or over and healthy adults.
- Live attenuated influenza vaccines (LAIVs) are currently not recommended for children under 2 years of age and adults, including older adults and those with comorbidities, because vaccine effectiveness has not been consistently demonstrated in these age groups.
- Because LAIV is a live-virus vaccine and data on its administration to pregnant women and the associated maternal and fetal risks are limited, LAIV is also not recommended during pregnancy.
- Inactivated influenza vaccine is safe to give throughout pregnancy.
- Co-administration of influenza vaccine, including with COVID-19 or live vaccines is acceptable. When 2 vaccines are administered at the same visit, the contralateral limb should be used.

Varicella:

- Countries with a high average age (≥15 years) of acquisition of infection could consider alternative vaccination strategies such as vaccination of adolescents and adults without evidence of varicella immunity. This strategy requires a 2-dose schedule.
- Varicella vaccination is contraindicated during pregnancy and pregnancy should be delayed for 4 weeks after vaccination.
- Termination of pregnancy is not indicated if vaccination was carried out inadvertently during pregnancy.
- Varicella vaccine can be administered concomitantly with other vaccines. Unless given together with other live viral vaccines (measles, MR, MMR), it should be administered at a minimum interval of 28 days.
- Countries should consider vaccination of potentially susceptible health-care workers (i.e., unvaccinated and with no history of varicella) with 2 doses of varicella vaccine.

Immunization of Health Care Workers:

- The following table summarizes all the required immunizations for healthcare workers[33]:

Table 17. Recommended Vaccines for Health Care Workers

Antigen	Vaccination of Health Care Workers Recommended
BCG[1]	BCG vaccination is recommended for unvaccinated TST- or IGRA-negative persons at risk of occupational exposure in low and high TB incidence areas (e.g. health-care workers, laboratory workers, medical students, prison workers, other individuals with occupational exposure)
Hepatitis B[2]	Immunization is suggested for groups at risk of acquiring infection who have not been vaccinated previously (for example HCWs who may be exposed to blood and blood products at work).
Polio[3]	All HCWs should have completed a full course of primary vaccination against polio.
Diphtheria[4]	HCWs who may have occupational exposure to *C. diphtheriae*. All health-care workers should up to date with immunization as recommended in their national immunization schedules.
Measles[5]	All HCWs should be immune to measles and proof/documentation of immunity or immunization should be required as a condition of enrollment into training and employment.
Rubella[6]	If rubella vaccine has been introduced into the national programme, all HCWs should be immune to rubella and proof/documentation of immunity or immunization should be required as a condition of enrollment into training and employment.
Meningococcal[7]	One booster dose 3-5 years after the primary dose may be given to persons considered to be at continued risk of exposure, including HCWs.
Influenza[8]	HCWs are an important group for influenza vaccination. Annual immunization with a single dose is recommended.
Varicella[9]	Countries should consider vaccination of potentially susceptible health-care workers (i.e. unvaccinated and with no history of varicella) with 2 doses of varicella vaccine
Pertussis[10]	HWCs should be prioritized as a group to receive pertussis vaccine.
Antigen	**No current recommendation for vaccination of Health Care Workers**
Tetanus[11]	There is currently no recommendation regarding HCWs.
Haemophilus influenzae type b[12]	The main burden of disease lies in infants under 5 years of age. Work in a health care setting is not indicated as a factor for increased risk. There is currently no recommendation regarding HCWs.
Pneumococcal[13]	The main burden of disease lies in infants under 5 years of age. Immunocompetent adults are not at increased risk for serious pneumococcal disease. HCWs are not indicated as a group at increased risk of pneumococcal disease.
Rotavirus[14]	Children are the target group for rotavirus vaccination as they have the greatest burden of disease. Adults including HCWs are not at increased risk of severe disease.
HPV[15]	HCWs are not at increased risk of HPV. The primary target group for vaccination is girls aged 9-14.
Japanese Encephalitis[16]	Health-care workers are generally not at special risk of contracting JE. Workers at high-risk in endemic areas, such as those involved in vector control, should be vaccinated.
Yellow Fever[17]	Individuals in endemic countries and travelers to these countries should receive a single dose of yellow fever vaccine. Work in a health care setting is not indicated as a factor for increased risk. There is currently no recommendation regarding HCWs.
Tick-borne Encephalitis[18]	Health-care workers are generally not at special risk of contracting JE. Workers at high-risk in endemic areas, such as those involved in vector control, should be vaccinated.
Typhoid[19]	Typhoid vaccines should be employed as part of comprehensive control strategies in areas where the disease is endemic. Work in a health care setting is not indicated as a factor for increased risk. There is currently no recommendation regarding HCWs.
Cholera[20]	Cholera vaccines may be employed as part of comprehensive control strategies in areas where the disease is endemic as well as to prevent and respond to cholera outbreaks[b]. There is currently no recommendation regarding HCWs.
Hepatitis A[21]	Hepatitis A is transmitted through contaminated food and water or direct contact with an infectious person. HCWs are not indicated as a group at increased risk of hepatitis A infection.
Rabies[22]	PrEP may be considered for medical professionals who regularly provide care to persons with rabies.
Mumps[23]	Routine mumps vaccination is recommended in countries with a well-established, effective childhood vaccination programme and the capacity to maintain high level vaccination coverage with measles and rubella vaccination. HCWs are not indicated as a group at increased risk.
Dengue (CYD-TDV)[24]	HCWs are not at increased risk of dengue
Malaria (RTS,S)[25]	Vaccine not recommended for adults. HWs are not at increased risk of malaria.

1.2.3 Australian National Immunization Program Schedule [2024]

The following guidelines do not provide a specified grade of evidence or level of recommendation.

The Australian Department of Health and Aged Care has established a National Immunization Program to be adapted in Australia; the recommendations are detailed below[34]:

The following table details all required adult immunizations:

Table 18. Adult Vaccination. Adapted from the Australian National Immunization Program Schedule (2024)

Age	Diseases	Vaccine Brand	Notes
All ages	Influenza (adults with specified medical risk conditions)	Age appropriate	Influenza vaccine: Administer annually. For information on age-appropriate vaccines or specified medical risk

	Influenza (Aboriginal and Torres Strait Islander adults)	Age appropriate	conditions refer to the Immunization Handbook or the annual ATAGI advice on seasonal influenza vaccines.
	Pneumococcal (adults with specified medical risk conditions)	Prevenar 13® and Pneumovax 23®	Pneumococcal vaccine: For people with specified medical risk conditions administer a dose of 13vPCV at diagnosis followed by 2 doses of 23vPPV. Refer to the Immunization Handbook for dose intervals.
	Shingles (herpes zoster) (adults with specified medical risk conditions)	Shingrix®	Shingles vaccine: For immunocompromised people aged 18 and older with specified medical risk conditions administer 2 doses. Refer to the Immunization Handbook for dose intervals.
50 years and over	Pneumococcal (Aboriginal and Torres Strait Islander adults)	Prevenar 13® and Pneumovax 23®	Administer a dose of 13vPCV, followed by first dose of 23vPPV 12 months later (2–12 months acceptable), then second dose of 23vPPV at least 5 years later
	Shingles (herpes zoster) (Aboriginal and Torres Strait Islander adults)	Shingrix®	Shingles vaccine: For Aboriginal and Torres Strait Islander people 50 years and older administer 2 doses. Refer to the Immunization Handbook for dose intervals.
65 years and over	Influenza (annually) (non-Aboriginal and Torres Strait Islander adults)	Age appropriate	Influenza vaccine: Administer annually. The adjuvanted influenza vaccine is recommended in preference to standard influenza vaccine. For information on age-appropriate vaccines refer to the Immunization Handbook

			or the annual ATAGI advice on seasonal influenza vaccines
	Shingles (herpes zoster) (non-Aboriginal and Torres Strait Islander adults)	Shingrix®	Shingles vaccine: For people 65 years and older administer 2 doses. Refer to the Immunization Handbook for dose intervals
70 years and over	Pneumococcal (non-Aboriginal and Torres Strait Islander adults)	Prevenar 13®	
Pregnant women	Pertussis (whooping cough)	Boostrix® or Adacel®	Pertussis vaccine: Single dose recommended each pregnancy, ideally between 20–32 weeks, but may be given up until delivery.
	Influenza	Age appropriate	Influenza vaccine: In each pregnancy, at any stage of pregnancy.

The following medical conditions have a heightened risk of development of influenza disease:

Table 19. Medical Conditions Associated with Increased Risk of Influenza Disease and Severe Outcomes

Conditions
Immunocompromising Conditions Including: • HIV Infection • Malignancy • Immunocompromise due to disease or treatment • Asplenia or splenic dysfunction • Solid Organ Transplant • Hematopoietic Stem Cell Transplant • CAR T-cell therapy
Cardiac Disease, Including: • Congenital Heart Disease • Congestive Heart Failure

- Coronary Artery Disease

Chronic Respiratory Conditions, Including:

- Suppurative Lung Disease
- Bronchiectasis
- Cystic Fibrosis
- Chronic Obstructive Pulmonary Disease
- Chronic Emphysema
- Severe Asthma (Requiring Frequent Medical Consultations or the Use of Multiple Medicines)

Chronic Neurological Conditions, Including:

- Hereditary And Degenerative CNS Diseases
- Seizure Disorders
- Spinal Cord Injuries
- Neuromuscular Disorders
- Conditions which increase respiratory infection risk

Chronic Metabolic Disorders, Including:

- Type 1 Or 2 Diabetes
- Amino Acid Disorders
- Carbohydrate Disorders
- Cholesterol Biosynthesis Disorders
- Fatty Acid Oxidation Defects, Lactic Acidosis
- Mitochondrial Disorders
- Organic Acid Disorders
- Urea Cycle Disorders
- Vitamin/Cofactor Disorders
- Porphyrias

Hematological Disorder

- Haemoglobinopathies

Chronic Kidney Disease

- Stage 4 or 5

Long-Term Aspirin Therapy In Children Aged 5 To 10 Years

Chronic Liver Disease

- Cirrhosis
- Autoimmune hepatitis
- Non-alcoholic fatty liver disease
- Alcoholic fatty liver disease

Chromosomal Abnormality
Obesity (Body Mass Index ≥30 Kg Per M^2)
Harmful Use of Alcohol

The following medical conditions have a heightened risk of development of pneumococcal disease:

Table 20. Medical Conditions Associated with Increased Risk of Pneumococcal Disease and Severe Outcomes

Conditions at Increased Risk of Pneumococcal Disease
Previous Episode of Invasive Pneumococcal Disease
Functional Or Anatomical Asplenia, Including • Sickle Cell Disease or Other Haemoglobinopathies • Congenital Or Acquired Asplenia (For Example, Splenectomy) Or Hyposplenia
Immunocompromising Conditions, Including • Congenital Or Acquired Immune Deficiency, Including Symptomatic IgG Subclass or Isolated IgA Deficiency • Hematological Malignancies • Solid Organ Transplant • Hematopoietic Stem Cell Transplant • HIV Infection • Immunosuppressive Therapy, Where Sufficient Immune Reconstitution for Vaccine Response Is Expected; This Includes Those with Underlying Conditions Requiring but Not Yet Receiving Immunosuppressive Therapy • Non-Hematological Malignancies Receiving Chemotherapy or Radiotherapy (Currently or Anticipated)
Proven Or Presumptive Cerebrospinal Fluid (CSF) Leak, Including • Cochlear Implants • Intracranial Shunts
Chronic Respiratory Disease, Including • Suppurative Lung Disease, Bronchiectasis and Cystic Fibrosis • Chronic Lung Disease in Preterm Infants • Chronic Obstructive Pulmonary Disease (COPD) And Chronic Emphysema • Severe Asthma (Defined as Requiring Frequent Hospital Visits or The Use Of Multiple Medications) • Interstitial And Fibrotic Lung Disease

Chronic Renal Disease • Relapsing Or Persistent Nephrotic Syndrome • Chronic Renal Impairment – eGFR <30 ml/min (Stage 4 or 5 Disease)
Cardiac Disease, Including • Congenital Heart Disease • Coronary Artery Disease • Heart Failure
Children Born Less Than 28 Weeks Gestation
Trisomy 21
Chronic Liver Disease, Including • Chronic Hepatitis • Cirrhosis • Biliary Atresia
Diabetes
Smoking (Current or in the Immediate Past)
Harmful Use of Alcohol (Consuming on Average ≥60 G Of Alcohol (6 Australian Standard Drinks) Per Day for Males And ≥40 G Of Alcohol (4 Australian Standard Drinks) Per Day For Females)

The following table describes the additional vaccinations for people with medical risk conditions:

Table 21. Additional Vaccination for People with Medical Risk Conditions

Age	Diseases	Vaccine Brand	Notes
All ages	Meningococcal ACWY	Nimenrix®	For people with asplenia, hyposplenia, complement deficiency and those undergoing treatment with eculizumab. Refer to the Immunization Handbook for dosing schedule. The number of doses required varies with age.
	Meningococcal B	Bexsero®	
≥ 6 months (annually)	Influenza	Age appropriate	For people with specified medical risk conditions that increases their risk of complications from

			influenza. Refer to the Immunization Handbook for information on age-appropriate vaccines.
≥ 12 months	Pneumococcal	Prevenar 13® and Pneumovax 23®	For people with specified medical risk conditions that increase their risk of pneumococcal disease, administer a dose of 13vPCV at diagnosis followed by 2 doses of 23vPPV. Refer to the Immunization Handbook for dose intervals.
≥ 5 years	*Haemophilus influenzae* type b (Hib)	Act-Hib®	For people with asplenia or hyposplenia, a single dose is required if the person was not vaccinated in infancy or incompletely vaccinated. (Note that all children aged <5 years are recommended to complete Hib vaccination regardless of asplenia or hyposplenia).

Special Populations:

People With Cancer:

- People with severe neutropenia:
    - People with severe neutropenia (absolute neutrophil count < 0.5×10^9 per L) should not receive any vaccines, to avoid an acute febrile episode.
- People receiving immune-oncology therapy:
    - People who are receiving cancer immuno-oncology therapies (checkpoint inhibitors) may have a higher risk of adverse events following immunization with influenza vaccine.

      Checkpoint inhibitors include: CTLA-4 inhibitors (such as ipilimumab) and PD-1 and PD-L1 inhibitors (such as nivolumab or pembrolizumab).
    - Live vaccines are not recommended for these patients.
    - Caution is advised with inactivated vaccines, particularly the influenza vaccine.

- Live vaccines for people with cancer:
    - Live vaccines are contraindicated in cancer patients who are receiving immunosuppressive therapy and/or who have poorly controlled malignant disease.
    - Seronegative people, who are at risk of these diseases, are recommended to receive these vaccines at least 3 months after they finish chemotherapy, provided that the underlying malignancy is in remission, and they are not severely immunocompromised.
- Inactivated vaccines for people with cancer:
    - People receiving chemotherapy may receive inactivated vaccines (such as pneumococcal conjugate vaccines [13vPCV, 15vPCV or 20vPCV] or hepatitis B) according to a routine or catch-up vaccination schedule. The immune response may be suboptimal, but it is safe for the person to receive these vaccines.
- HPV vaccine:
    - If the person needs HPV vaccine, 9vHPV (9-valent HPV) vaccine is recommended in a 3-dose schedule (0, 2, 6 months). This is regardless of the person's age at the start of vaccination.
- Influenza vaccine:
    - All cancer patients aged ≥6 months are recommended to receive influenza vaccine each year.
    - Cancer patients who have had a hematopoietic stem cell transplant or solid organ transplant and are receiving influenza vaccine for the 1st time after transplant are recommended to receive 2 vaccine doses at least 4 weeks apart (irrespective of age), and 1 dose each year after that.
- Pneumococcal vaccine:
    - People with underlying hematological and other generalized malignancies are recommended to receive pneumococcal vaccine.
    - Children or adults who are newly diagnosed with cancer are recommended to receive 1 dose of a pneumococcal conjugate vaccine (13vPCV or 15vPCV or 20vPCV) and 2 doses of 23vPPV (23-valent pneumococcal polysaccharide vaccine).
- Zoster vaccine:
    - All cancer patients who are immunocompromised and aged ≥18 years are recommended to receive 2 doses of recombinant zoster vaccine (Shingrix) 1-2 months apart.

- COVID-19 vaccine:
    - Cancer patients who are severely immunocompromised are recommended to receive a 3rd dose of COVID-19 vaccine.
    - Recommendations for additional booster doses are based on a patient's degree of immunocompromise, age and presence of other risk factors.
- Respiratory Syncytial Virus Vaccine:
    - Cancer patients aged ≥60 years are recommended to receive a single dose of an RSV vaccine.
- People who have completed cancer therapy:
    - People who have finished cancer therapy and who completed a primary vaccination schedule before diagnosis can receive most of the following vaccines without having their antibody titers checked beforehand.
    - If the person is well and in remission for 6 months after therapy, they are recommended to receive the following booster doses after they have completed their primary vaccination schedule:
        - DTPa (diphtheria-tetanus-acellular pertussis)–containing and IPV (inactivated poliovirus)–containing vaccines: Single dose of either dT or reduced antigen content dTpa if ≥10 years of age, and a single dose of IPV.
        - MMR-containing vaccine: Single dose, followed by antibody testing for immunity to measles and rubella at 6–8 weeks after vaccination. People who have not seroconverted are recommended to receive an extra dose.
        - Hepatitis B vaccine: Single dose.
        - Pneumococcal vaccines: If the full course was not received previously a single dose of a pneumococcal conjugate vaccine (13vPCV or 15vPCV or 20vPCV) and 2 doses of 23vPPV after the conjugate vaccine.
        - Hib (Haemophilus influenzae type b) vaccine: Single dose if ≥ 5 years of age with asplenia.
        - Meningococcal vaccine: Single dose of MenACWY. Revaccination with MenACWY is recommended every 5 years for people with asplenia. Single dose of MenB.

- 9vHPV vaccine: If no previous doses received, a single dose is recommended if commencing vaccination before the 26th birthday and no longer immunocompromised. A 3-dose schedule (0, 2, 6 months) is recommended if commencing vaccination from 26 years of age or if still immunocompromised.
- Varicella vaccine: People who are seronegative for varicella-zoster virus should receive a 2-dose schedule of varicella vaccine, at least 6 months after chemotherapy has finished.
- Respiratory Syncytial Virus Vaccine: Single dose for people aged ≥60 years.

Solid Organ Transplant Recipients:

The following table describes immunization recommendations for patients before and after a solid organ transplant:

Table 22. Vaccine Recommendations for Patients Before and After Solid Organ Transplantation

Vaccine	Before transplantation	After transplantation, (if full vaccine course not given beforehand)	Comments
dTpa for those ≥ 10 years of age	Yes	Yes	• Recipients ≥10 years of age and not previously vaccinated should receive the 1st dose as dTpa, followed by 2 doses of dT. • If dT is unavailable, complete vaccination course with dTpa. • Adults who have received at least 3 primary doses of a diphtheria-tetanus-pertussis–containing vaccine should receive a dose of dTpa after transplant if their last dose was more than 10 years ago.
Hepatitis A vaccine	Yes, if seronegative	Yes, if seronegative	Recommended for: • all liver solid organ transplant recipients • transplant candidates or recipients with chronic liver disease • those chronically infected with either hepatitis B or hepatitis C
Hepatitis B vaccine	Yes, if seronegative	Yes, if seronegative	• Recommended for all seronegative solid organ transplant candidates. • Immunogenicity is likely to be improved when candidates receive the vaccine before transplantation. • Can use an accelerated schedule before transplantation.

9vHPV (9-valent human papillomavirus vaccine)	Yes	Yes	• 1 dose is recommended for people who are immunocompetent and start vaccination before their 26th birthday. • 3-dose schedule (0, 2, 6 months) is recommended for people who are immunocompetent and start vaccination after their 26th birthday. • If a person has a solid organ transplant before completing the course, a 3-dose schedule is recommended. • 3-dose schedule (0, 2, 6 months) of 9vHPV is recommended for people who are vaccinated after transplant. • For people >25 years of age, conduct a risk assessment to determine their need for vaccination.
IPV (inactivated poliovirus) vaccine	Yes	Yes	• Adults who have received a routine course of polio vaccination in childhood are recommended to receive a booster every 10 years if they plan to travel to a polio-endemic area or have an occupational risk of polio exposure (e.g. laboratory workers).
Influenza vaccine	Yes (1 dose every year for people ≥ 6 months of age)	Yes (2 doses in 1st year after transplant, followed by 1 dose yearly)	• 2 doses in 1st year after transplant should be given 4 weeks apart.

MenB (meningococcal B) vaccine	Yes, if at risk due to age or other defined risk factors	Yes, if at risk due to age or other defined risk factors	• MenB vaccine is recommended for certain age groups and individuals with specific risk factors placing them at increased risk of invasive meningococcal disease. • The number of doses varies with age.
MenACWY (quadrivalent meningococcal conjugate) vaccine	Yes	Yes	• MenACWY is recommended for certain age groups and individuals with specific risk factors placing them at increased risk of invasive meningococcal disease • The number of doses varies with age.
MMR (measles-mumps-rubella) vaccine	Yes (at least 1 month before transplantation, if possible)	Contraindicated	• Confirm immunity by serological testing before transplantation. • If seronegative, complete a 2-dose primary vaccination schedule for children and adults before transplantation, provided the person is not immunocompromised at that time.
PCV (pneumococcal conjugate vaccine) - 13vPCV, 15vPCV or 20vPCV ~~[if ≥18 years of age]~~	Yes	Yes	• 1 dose (in addition to those routinely offered in childhood).
23vPPV (23-valent pneumococcal	Yes (2–12 months after a dose of PCV (pneumococcal conjugate	Yes (2–12 months after a dose of PCV (13vPCV, 15vPCV or 20vPCV)	• 2 doses at least 5 years apart.

polysaccharide vaccine)	vaccine [13vPCV, 15vPCV or 20vPCV]))		
Varicella vaccine	Yes, (at least 1 month before transplantation, if possible)	Contraindicated	• Confirm immunity by serological testing before transplantation. • If seronegative, complete a 2-dose primary vaccination schedule for children and adults before transplantation, provided the person is not immunocompromised at that time.
Recombinant zoster vaccine (Shingrix)	Yes (complete 2-dose schedule at least 1 month before transplantation, if possible)	Yes	• 2 doses 2-6 months apart prior to transplantation. • 2 doses 1-2 months apart following transplantation. • Shingrix is registered for people aged ≥18 years who are immunocompromised. • Vaccination post-transplant and cessation of anti-viral prophylaxis is preferred.
COVID-19 vaccine	Yes, if not already received	Yes	Recommendations for additional doses after transplantation are based on an individual's degree of immunocompromise, age and presence of other risk factors for severe illness.
Respiratory syncytial virus (RSV) vaccine	Yes, if not already received	Yes	RSV vaccine is recommended for people aged ≥60 years with medical conditions that increase their risk of severe RSV disease, such as solid organ transplant recipients.

People with HIV:

- People with HIV should have vaccination schedules based on their:
    - Age
    - CD4+ count (which indicates how immunocompromised they are)
    - Risk of infection
    - Concurrent medical conditions or medications (which may be immunocompromising)
- Live attenuated vaccine considerations for people with HIV:
    - **BCG Vaccine**
        - Children or adults with HIV should not receive BCG vaccine, because of the risk of disseminated BCG infection.
    - **Live Cholera Vaccine**
        - People with HIV should not receive oral live attenuated cholera vaccine. Use the inactivated oral cholera vaccine instead.
    - **Japanese Encephalitis Vaccine**
        - People with HIV who need Japanese encephalitis vaccine should not receive the live attenuated recombinant vaccine (Imojev).
        - They should receive the inactivated vaccine (JEspect) instead.
    - **MMR Vaccine**
        - Asymptomatic adults with HIV should receive 1 or 2 doses of MMR vaccine if they have a $CD4^+$ count ≥ 200 per μL and are seronegative for any of the vaccine components.
        - The number of doses depends on the number of previous doses and whether they seroconvert.
        - MMR vaccine does not have a significant effect on the $CD4^+$ count or viral load of adults with HIV.
        - People with HIV are not recommended to receive the combination MMRV vaccine.
    - **Mpox Vaccine**
        - People living with HIV can receive replication-deficient live attenuated mpox vaccine, MVA-BN (JYNNEOS), although the immune response may be reduced.
    - **Typhoid Vaccine**

        - People with HIV should not receive oral live attenuated typhoid vaccine. They should be given the inactivated parenteral Vi polysaccharide typhoid vaccine instead.
    - **Varicella Vaccine**
        - Asymptomatic adults and children ≥12 months old with HIV may receive the varicella vaccine.
        - Adults with HIV who are varicella seronegative and have a $CD4^+$ count of ≥200 per μL are recommended to receive 2 doses of monovalent varicella vaccine at least 3 months apart.
        - People with HIV are not recommended to receive the combination MMRV vaccine.
    - **Yellow Fever Vaccine**
        - People with HIV who are not immunocompromised ($CD4^+$ count of >200 per μL) can receive yellow fever vaccine if they are at risk of infection. People with HIV should only receive yellow fever vaccine if potential exposure to yellow fever virus is unavoidable.
    - **Live Zoster Vaccine (Zostavax)**
        - Adults with symptomatic HIV infection are not recommended to receive Zostavax.
        - People aged ≥ 50 years with asymptomatic HIV infection can receive Zostavax, if recombinant zoster vaccine (Shingrix) is not accessible, and if they; are on antiretroviral therapy, have a very low or undetectable viral load, and have a $CD4^+$ count of ≥ 350 per μL.
        - If there is a strong indication to vaccinate, some experts suggest that adults with a $CD4^+$ count of >200 per μL can safely receive Zostavax.
        - Zostavax is only registered for use in adults ≥50 years of age.
- **Inactivated Vaccines for People with HIV:**
    - **Meningococcal Vaccines**
        - People with HIV are recommended to receive MenACWY and MenB vaccines.
        - People with HIV may have a diminished immune response after a single dose of MenACWY. However, this improves for some serogroups after a 2nd dose.

        - There are no clinical data on the use of MenB vaccine in people with HIV. Vaccination is recommended based on the expected benefit in these people.
    - **HPV Vaccine**
        - Adults with HIV can receive the 9vHPV vaccine.
        - HPV vaccines are safe and immunogenic in people with HIV.
        - People with HIV are recommended to receive a 3-dose course of 9vHPV vaccine at 0, 2 and 6 months regardless of their age when they started vaccination.
        - Males aged 27–45 years who receive HPV vaccine are unlikely to have different immunogenicity or adverse events compared with females in this age group, for whom the vaccine is currently registered. However, these men may have less benefit if they have already been infected with HPV.
    - **DTPa/dTpa, Hib and IPV Vaccines**
        - People with HIV can receive DTPa or dTpa, Hib and IPV vaccines according to routine recommendations.
    - **Hepatitis A Vaccine**
        - Hepatitis A vaccine is only recommended for use in non-immune people with HIV if they have independent risk factors for acquiring hepatitis A.
    - **Hepatitis B Vaccine**
        - People with HIV can safely receive hepatitis B vaccine.
        - Because of immune suppression, they may have a diminished immunological response.
        - Limited studies in HIV1-positive adults show an improved and accelerated serological response to a vaccination schedule that comprises 4 double doses. This means 2 injections of the standard adult dose (using Engerix-B) on each occasion, at 0, 1, 2 and 6 months.
    - **Influenza Vaccine**
        - All adults and children (≥ 6 months of age) with HIV are recommended to receive influenza vaccine every year.

- **Pneumococcal Vaccine**
    - Children aged > 12 months and adults who are newly diagnosed with HIV are recommended to receive a single dose of a pneumococcal conjugate vaccine (PCV) (13vPCV, 15vPCV or 20vPCV), followed by 2 doses of 23vPPV. If they have previously received doses of 23vPPV, they are recommended to receive the dose of the pneumococcal conjugate vaccine 12 months after their last 23vPPV dose. If they have already received at least 2 doses of 23vPPV, no further 23vPPV doses are recommended.
- **Q fever Vaccine**
    - There are no data on Q fever vaccine in people with HIV.
    - Q fever vaccine is contraindicated in people who are immunocompromised.
- **Typhoid, Japanese Encephalitis and Rabies Vaccines**
    - People with HIV can safely receive the following vaccines if they are travelling or living in an at-risk area:
    - Parenteral Vi Polysaccharide Typhoid Vaccine
    - Inactivated oral cholera vaccine (Dukoral)
    - Inactivated Japanese Encephalitis Vaccine (Jespect)
    - Rabies Vaccine
- **Recombinant Zoster Vaccine (Shingrix)**
    - People aged ≥18 with HIV can safely receive recombinant zoster vaccine (Shingrix), and this is the preferred zoster vaccine for this population.
- **COVID-19 Vaccine**
    - People with HIV who have CD4 counts < 250/μL, or those with a higher CD4 count unable to be established on effective antiretroviral therapy (ART) are recommended to receive a 3rd primary dose of COVID-19 vaccine.
    - A 3rd primary dose is not required for people receiving ART who have CD4 counts ≥ 250/μL.
    - Additional doses may be required based on age, degree of ongoing immunosuppression and presence of other risk factors for severe illness.

- **Respiratory Syncytial Virus Vaccine**
  - People aged ≥60 years with HIV are recommended a single dose of RSV vaccine.

People with Autoimmune Diseases and Other Chronic Conditions:

- People with autoimmune conditions are at higher risk of vaccine-preventable diseases, and associated morbidity and mortality. Examples of these conditions are:
  - Systemic Lupus Erythematosus
  - Rheumatoid Arthritis
  - Inflammatory Bowel Disease
  - Multiple Sclerosis
- These people are also at risk of infection as a result of treatment with immunosuppressive agents such as corticosteroids and DMARDs (disease-modifying anti-rheumatic drugs).
- People with autoimmune diseases and other chronic conditions are recommended to receive inactivated vaccines to optimize protection against disease.
- There is potential for reduced immunogenicity of vaccines in these people due to both immunosuppressive treatment and the underlying disease.
- Extra vaccine doses, such as for pneumococcal vaccine, may be needed.
- Live vaccines are generally contraindicated in people who are receiving immunosuppressive therapy, such as DMARDs and high-dose corticosteroids.
- People should receive all indicated live vaccines at least 1 month before starting immunosuppressive therapy, if possible.
- In general, people who are immunocompromised and receiving biological DMARDs (bDMARDs) or targeted synthetic DMARDs (tsDMARDs) should not receive live vaccines until at least 12 months after therapy has ended.
- Association between vaccines and autoimmune conditions, such as Guillain–Barré syndrome:
  - Overall, theoretical concerns that vaccines exacerbate or cause autoimmune diseases such as rheumatoid arthritis, type 1 diabetes and multiple sclerosis have not been substantiated.
  - In almost all cases, people with autoimmune disease can safely receive inactivated vaccines.

    - People with a history of GBS whose first episode was not after influenza vaccination have an extremely low risk of recurrence of GBS after vaccination; Influenza vaccination is recommended for these people.
    - Influenza vaccination is generally not recommended for people with a history of GBS whose first episode occurred within 6 weeks of receiving an influenza vaccine.
- Hypopituitarism:
    - Hypopituitarism is not a contraindication to vaccination if the person is only receiving physiological corticosteroid replacement for their condition.
    - If the person has been unwell and is on high-dose corticosteroids for more than 14 days, do not give live vaccines for at least 1 month after stopping therapy.
- Metabolic diseases:
    - People with metabolic diseases should receive vaccines using the routine schedule. Vaccination is generally considered safe in these people.
    - Influenza and pneumococcal vaccines are recommended for people with chronic medical conditions, such as metabolic disease.

1.2.4 Canada's Improving Adult Immunization [2025]

The following guidelines do not provide a specified grade of evidence or level of recommendation.

Government of Canada has issued a Canadian Immunization Guide for adults; the recommendations are detailed below[35]:

The following table summarizes the recommendations for routine immunization in healthy adults at low risk:

Table 23. Routine Immunization in Healthy Adults at Low Risk

Vaccine	Recommendations for Routine Immunization
Diphtheria, Tetanus	• Primary series for previously unimmunized adults • Booster dose every 10 years
Herpes zoster (shingles)	• 50 years of age and older - 2 doses RZV • 50 years of age and older previously received LZV - 2 doses RZV, at least 1 year after immunization with LZV

	• 50 years of age and older previous episode of HZ - 2 doses RZV, at least 1 year after episode of HZ
Human papillomavirus (HPV)	• Individuals up to and including 20 years of age - 1 dose • Individuals 21 years of age and older – 2 doses
Influenza	Annually
Measles, mumps	• Susceptible adults born in or after 1970 - 1 dose • Born before 1970 - consider immune
Meningococcal conjugate	Adults up to and including 24 years of age not immunized in adolescence - 1 dose
Pertussis	• One dose of acellular pertussis-containing vaccine in adulthood • Adults who will be in close contact with young infants should be immunized as early as possible • One dose of Tdap vaccine should be administered in every pregnancy, ideally between 27 and 32 weeks of gestation.
Pneumococcal conjugate 20 valent	65 years of age and older - 1 dose
Pneumococcal conjugate 21 valent	• One dose of either Pneu-C-20 or Pneu-C-21, regardless of pneumococcal vaccination history with Pneu-C-13, Pneu-C-15 or Pneu-P-23, should be given to: o Adults 65 years of age and older o Adults under 65 years of age at increased risk of Invasive Pneumococcal Disease (IPD)
Polio	• Primary series for previously unimmunized adults when a primary series of tetanus toxoid- and diphtheria toxoid-containing vaccine is being given or with routine tetanus toxoid- and diphtheria toxoid- containing vaccine booster doses
Rubella	• Susceptible adults - 1 dose • If vaccine is indicated, pregnant women should be immunized after delivery
Varicella (chickenpox)	• Susceptible adults up to and including 49 years of age - 2 doses; if only one dose was previously received, a second dose should be provided • Known seronegative adults 50 years of age and older - 2 doses - routine testing is not advised

The following table summarizes the immunization recommendations for specific risk situations:

Table 24. Vaccine Recommendations for adults at Risk Situations

Vaccine	Recommendations for Risk Situations
Bacille Calmette-Guérin (BCG)	Consider use for adults: • Who may be repeatedly exposed to persons with untreated, inadequately treated or drug-resistant active tuberculosis (TB) in conditions in which protective measures against infection are not feasible and when early identification and treatment of latent TB infection are not available • Who are long-term travelers to high prevalence countries (in exceptional circumstances as noted above)

Cholera and travelers' diarrhea	• Consider use for **cholera prevention** in adult travelers to cholera-endemic area(s) at high risk of exposure, including those with occupational risk for exposure (e.g., health care or humanitarian workers in endemic countries)
	• Consider use for **prevention of travelers' diarrhea** in adults:
	  ○ With chronic diseases at risk for complications
	  ○ At increased risk of acquiring travelers' diarrhea
	  ○ Who are immunosuppressed
	  ○ With a history of repeated severe travelers' diarrhea

Ebola virus	Recommended for adults: • A single dose of Ebola Zaire vaccine (EZV) is recommended for non-pregnant and immunocompetent individuals 18 years of age or older following exposure to Ebola virus in Canada.
***Haemophilus influenzae* type b (Hib)**	Recommended following hematopoietic stem cell transplantation (HSCT) and for adults with increased risk of invasive Hib disease: • Congenital (primary) immunodeficiencies • Malignant hematologic disorders • HIV • Anatomic or functional asplenia or hyposplenism

	• Solid organ transplant recipients • Cochlear implant recipients
Hepatitis A (HA)	Recommended for adults: • Travelling to HA endemic areas • Who are immigrants from HA endemic areas • Who are household or close contacts of children adopted from HA endemic countries • In communities or populations at risk of outbreaks or in which HA is highly endemic • Who are household or close contacts of proven or suspected cases of HA • With occupational or lifestyle risk for exposure • With chronic liver disease from any cause, including those infected with hepatitis B and C • Receiving plasma-derived replacement clotting factors
Hepatitis B (HB)	Recommended for adults: • Who have immigrated to Canada from areas where there is a high prevalence of HB and are known to be susceptible to HB • Who are household or sexual contacts of acute HB cases and HB carriers, including close contacts of children adopted from HB endemic countries if the adopted child is HbsAg positive • With occupational or lifestyle risk for exposure • Travelling to HB endemic areas • In communities or populations in which HB is highly endemic • Who are residents of institutions for the developmentally challenged or inmates of correctional facilities • With chronic liver disease, including those infected with hepatitis C • With chronic renal disease, including patients on chronic dialysis • Hemophiliacs and other people who receive repeated infusions of blood or blood products • Who have undergone hematopoietic stem cell transplantation or are awaiting solid organ transplant

	• Who have congenital immunodeficiencies • Who are HIV-infected
Herpes Zoster (shingles)	• RZV may be considered for immunocompromised adults 50 years of age and older based on a case-by-case assessment of the benefits vs risks.
Human Papillomavirus (HPV)	• HPV vaccine may be considered for individuals 27 years of age and older at ongoing risk of exposure with shared decision making and discussion with a healthcare provider.
Influenza	Recommended annually for all adults, with focus on adults: • At high risk of influenza-related complications • Capable of transmitting influenza to individuals at high risk • Who provide essential community services • In direct contact during culling operations with poultry infected with avian influenza
Japanese encephalitis	Recommended for adults: • With occupational risk for exposure • Travelling to endemic area(s) during transmission season with specified exposure risks Booster dose 12 months after primary immunization for persons at continuous risk
Measles, mumps	• Recommended for adults born in or after 1970: o If susceptible and at increased risk of exposure (travelers to destinations outside of Canada, health care workers, students in post-secondary educational settings, and military personnel) - 2 doses, at least 4 weeks apart. • Recommended for adults born before 1970 if: o Non-immune military personnel or health care workers - 2 doses, at least 4 weeks apart o Non-immune travelers - 1 dose o Non-immune students - consider 1 dose
Meningococcal conjugate quadrivalent, Multicomponent meningococcal	Recommended for adults: • With occupational risk for exposure (i.e., laboratory workers; military personnel during recruit training and on deployments during which the risk of infection is elevated)

	• Who are travelers:
	  ○ For whom meningococcal vaccine is recommended or required, including travelers to sub-Saharan African and pilgrims to the Hajj in Mecca, Saudi Arabia
	  ○ To an area with a hyperendemic strain or an outbreak that is known to be caused by a serogroup that can be prevented by the vaccine
	• At high risk of meningococcal disease due to medical conditions:
	  ○ Anatomic or functional asplenia or hyposplenism (including sickle cell disease)
	  ○ Congenital complement, properdin, factor D or primary antibody deficiencies
	  ○ Acquired complement deficiency due to receipt of the terminal complement inhibitor eculizumab
	  ○ Should be considered for adults who are HIV-infected
	• Who are close contacts of a case of invasive meningococcal disease caused by a vaccine preventable serogroup

Pneumococcal conjugate 20-valent	Recommended for adults with the following medical, environmental or living conditions: • Immunodeficiencies, including B-lymphocyte (humoral) immunity, T-lymphocyte (cell) mediated immunity, complement system (properdin, or factor D deficiencies), or phagocytic functions • Immunocompromising therapy, including use of long-term corticosteroids, chemotherapy, radiation therapy, and post-organ transplant therapy • HIV infection • Hematopoietic stem cell transplant (recipient) • Malignant neoplasms, including leukemia and lymphoma • Solid organ or islet transplant (recipient) • Chronic kidney disease, particularly those with nephrotic syndrome, on dialysis or with renal transplant • Chronic liver disease, including biliary atresia and hepatic cirrhosis due to any cause

	• Functional or anatomic asplenia, including sickle cell disease and other hemoglobinopathies • Chronic cerebrospinal fluid (CSF) leak • Cochlear implants, including those who are to receive implants • Chronic neurologic conditions that may impair clearance of oral secretions • Chronic heart disease, including congenital heart disease and cyanotic heart disease • Diabetes mellitus • Chronic lung disease, including asthma requiring medical care in the preceding 12 months • Who are underhoused or experiencing homelessness • Who live in communities or settings experiencing sustained high IPD rates • Who smoke • With substance use disorders (i.e., cocaine use and injection drug use) • With alcohol use disorder • Who are in residential care, including long-term care homes
Polio	Recommended for: • Adults travelling to, or receiving travelers from, areas where poliovirus is known or suspected to be circulating • Health care workers who have close contact with individuals who might be excreting wild type or vaccine type poliovirus • Members of communities or specific population groups with disease caused by polio • People who come in close contact with those who may be excreting poliovirus such as people working with refugees, military personnel and people on humanitarian missions in endemic countries • Laboratory workers handling specimens that may contain poliovirus • Family or close contacts of internationally adopted infants who may have been or will be vaccinated with oral polio vaccine (OPV) For previously unimmunized adults - primary series of IPV-containing vaccine

	For previously immunized adults - one lifetime booster dose of IPV-containing vaccine
Rabies	Recommended for pre-exposure prophylaxis for adults: • With occupational risk of exposure • With lifestyle risk of exposure • Travelling to high-risk areas with specified exposure risks
Respiratory syncytial virus (RSV)	Recommended for adults: • 75 years of age and older, particularly for those who are at increased risk of severe RSV disease because of chronic health conditions, including: o Cardiac or pulmonary disorders o Diabetes mellitus and other metabolic diseases o Moderate and severe immunodeficiency o Chronic renal disease o Chronic liver disease o Certain neurologic or neurodevelopmental conditions o Class 3 obesity (defined as body mass index of 40 kg/m^2 and over) • 60 years of age and older who are residents of nursing homes and other chronic care facilities. RSV immunization may be considered as an individual decision for adults 60 to 74 years of age in consultation with their health care provider RSV immunization, using RSVpreF vaccine, may be considered by pregnant women and pregnant people who are 32 to 36 wGA to protect their infants from RSV.
Smallpox	Recommended only for adults with a specific occupational risk of exposure to the smallpox virus
Typhoid	Recommended for adults: • Travelling to endemic area(s) with specified exposure risks • Who have ongoing household or intimate exposure to a *S. Typhi* carrier • With occupational risk of exposure Booster doses if at ongoing risk
Yellow fever	Recommended for healthy adults:

	• Less than 60 years of age travelling to areas where there is evidence of yellow fever (YF) transmission or if the vaccine is required for foreign travel • With occupational risk of exposure Consider immunization of healthy adults aged 60 years and over if travel to areas with risk of yellow fever transmission cannot be avoided and a high level of protection against mosquito exposure is not feasible. Based on a case-by-case assessment of benefit versus risk, the use of a **one-time** booster dose is recommended for certain individuals. Re-immunization every 10 years is recommended for: • Laboratory personnel working with YF virus unless measured neutralizing antibody titer to yellow fever virus confirms ongoing protection • HIV-positive individuals who are travelling to countries with risk of YF transmission

COVID-19 Recommendations:

The following table details the COVID-19 adult-specific immunization schedule:

Table 25. Immunization Schedule for Previously Unvaccinated Individuals by Age Starting Their Vaccinations with Authorized 2024-2025 COVID-19 Vaccines (That Are or May be Available)

Age group	Immunization schedule	Products	Recommended interval
Schedule for those not moderately or severely immunocompromised			
12 years of age and older	1-dose	• 50 mcg Moderna Spikevax • 30 mcg Pfizer-BioNTech Comirnaty • 5 mcg Novavax Nuvaxovid	Not applicable
Schedule for individuals who are moderately to severely immunocompromised			

Age group	Immunization schedule	Products	Recommended interval
12 years of age and older	2 doses are recommended and a third may be offered	• 50 mcg Moderna Spikevax • 30 mcg Pfizer-BioNTech Comirnaty • 5 mcg Novavax Nuvaxovid	4 to 8 weeks

- Immunization is particularly important for those at increased risk of COVID-19 infection or severe disease, for example:
    - Adults 65 years of age or older
    - Residents of long-term care homes and other congregate living settings
    - Individuals with underlying medical conditions that place them at higher risk of severe COVID-19
    - Individuals who are pregnant
    - Individuals in or from First Nations, Métis and Inuit communities
    - Members of racialized and other equity-deserving communities
    - People who provide essential community services
- For Pregnant and Breastfeeding patients:
    - Either mRNA or protein subunit vaccines may be used for people who are pregnant. However, there is more data available for mRNA vaccines than the protein subunit vaccine for people who are pregnant.
    - It is recommended that beginning in the fall of 2024, previously vaccinated and unvaccinated pregnant individuals at increased risk of SARS-CoV-2 infection or severe COVID-19 disease should be vaccinated with a JN.1 or KP.2 COVID-19 vaccine.
- For Immunocompromised patients:
    - For those who are moderately to severely immunocompromised, the primary series of updated 2024-2025 COVID-19 vaccines is as follows, with an interval of 4 to 8 weeks between doses:
        - For those 5 years of age and over: 2 doses are recommended and a third dose may also be offered.

Section 2.0 Drug Therapy (Vaccines)

This section comprises four subsections: the first contains the newly recommended vaccines, the second covers modifications, the third one outlines the vaccines that have been withdrawn from the market, and the fourth details FDA/EMA approved vaccines that are not SFDA registered.

2.1 Additions

The following vaccines have been newly approved for Adult Immunization; some of which are SFDA registered, and others are not. The first section below tackles the SFDA registered new molecules along with their HTA analysis and the second section includes non-SFDA registered new molecules.

2.1.1 Pneumococcal Vaccines

2.1.1.1 Vaxneuvance (Pneumococcal 15-Valent Conjugate Vaccine)

Information on the vaccine are detailed below[36,37]:

Table 26. Vaxneuvance® Drug Information

SCIENTIFIC NAME **Pneumococcal Conjugate Vaccine (15-Valent)**	
SFDA Classification	Prescription
SFDA Approval	Yes
US FDA	Yes
EMA	Yes
MHRA	Yes
PMDA	Yes
Indication (ICD-10)	Z23, Z24, Z25, Z26, Z27
Drug Class	Vaccine
Drug Sub-class	Vaccine, Inactivated (Bacterial)
ATC Code	J07AL02
Pharmacological Class (ASHP)	80:12 - Vaccines
DRUG INFORMATION	
Dosage Form	Suspension Prefilled Syringe, Intramuscular
Route of Administration	Intramuscular use

Dose (Adult) [DDD]*	Vaxneuvance® is to be administered as a single dose of 0.5 mL in adults 18 years of age and older.
Maximum Daily Dose Adults*	N/A
Adjustment	There are no dosage adjustments provided in the manufacturer's labeling.
Prescribing edits*	AGE, QL, PE
AGE (Age Edit)	The safety and effectiveness of Vaxneuvance® in individuals younger than 6 weeks of age have not been established.
CU (Concurrent Use Edit)	N/A
G (Gender Edit)	N/A
MD (Physician Specialty Edit)	N/A
PA (Prior Authorization)	N/A
QL (Quantity Limit)	Single dose
ST (Step Therapy)	N/A
EU (Emergency Use Only)	N/A
PE (Protocol Edit)	Vaxneuvance® is to be administered as a single dose in adults 18 years of age and older.
SAFETY	
Main Adverse Drug Reactions (Most common and most serious)	**Most common:** Erythema at injection site, pain at the injection site, fatigue, headache. **Most serious:** Arthralgia, myalgia, urticaria.
Drug Interactions*	**Category X:** Elivaldogene Autotemcel
Special Population	**Altered immunocompetence:** Postpone vaccination during periods of severe immunosuppression (e.g., patients receiving chemo-/radiation therapy or other immunosuppressive therapy [including high-dose corticosteroids]) if appropriate; may have a reduced response to vaccination. In general, household and close contacts of persons with altered

	immunocompetence may receive all age-appropriate vaccines. Nonlive vaccines should be administered ≥2 weeks prior to planned immunosuppression when feasible; nonlive vaccines administered during chemotherapy should be readministered after immune competence is regained. **Premature infants:** Apnea following IM vaccination has been observed in some preterm infants; consider clinical status implications.
Pregnancy	Nonlive bacterial vaccines have not been shown to cause increased risks to the fetus. Although specific recommendations for vaccination of pregnant patients is not available, pneumococcal vaccines may be administered during pregnancy in persons at increased risk of severe disease due to underlying medical conditions.
Lactation	According to the manufacturer, the decision to breastfeed following immunization should consider the risk of infant exposure, the benefits of breastfeeding to the infant, and the benefits of vaccination to the mother. Nonlive vaccines have not been shown to affect the safety of the breastfed infant or mother. Breastfeeding infants should be vaccinated according to the recommended schedules.
Contraindications	Severe hypersensitivity (e.g., anaphylaxis) to pneumococcal conjugate vaccine, any component of the formulation, or to diphtheria toxoid.
Monitoring Requirements	Monitor for hypersensitivity and syncope for 15 minutes following administration. If seizure-like activity

	associated with syncope occurs, maintain patient in supine or Trendelenburg position to reestablish adequate cerebral perfusion.
Precautions	**Anaphylactoid/hypersensitivity reactions:** Immediate treatment (including epinephrine 1 mg/mL) for anaphylactoid and/or hypersensitivity reactions should be available during vaccine use. **Shoulder injury related to vaccine administration:** Vaccine administration that is too high on the upper arm may cause shoulder injury (e.g., shoulder bursitis, tendinopathy) resulting in shoulder pain and reduced range of motion following injection. Use proper injection technique for vaccines administered in the deltoid muscle (e.g., injecting in the central, thickest part of the muscle) to reduce the risk of shoulder injury related to vaccine administration. **Syncope:** Syncope has been reported with use of injectable vaccines and may result in serious secondary injury (e.g., skull fracture, cerebral hemorrhage); typically reported in adolescents and young adults and within 15 minutes after vaccination. Procedures should be in place to avoid injuries from falling and to restore cerebral perfusion if syncope occurs. **Acute illness:** The decision to administer or delay vaccination because of current or recent febrile illness depends on the severity of symptoms and the etiology of the disease. Postpone administration in patients with moderate or severe acute illness (with or without fever); vaccination

	should not be delayed for patients with mild acute illness (with or without fever). **Bleeding disorders:** Use with caution in patients with bleeding disorders (including thrombocytopenia); bleeding/hematoma may occur from IM administration; if the patient receives antihaemophilia or other similar therapy, IM injection can be scheduled shortly after such therapy is administered.
Black Box Warning	N/A
REMS*	N/A

HEALTH TECHNOLOGY ASSESSMENT (HTA)

The table below lists the HTA reviews and recommendations of Adult Immunization vaccines by the following agencies/institutes/authorities: National Institute for Health and Care Excellence (NICE), Canada's Drug Agency (CDA), Haute Autorité de Santé (HAS), Institute for Quality and Efficiency in Health Care (IQWIG), and Pharmaceutical Benefits Advisory Committee (PBAC) as applicable. **The recommendations below are for Pneumococcal Conjugate Vaccine (15-Valent).**

Table 27. Vaxneuvance® HTA Analysis

MEDICATION	AGENCY	DATE – HTA RECOMMENDATION
Pneumococcal Conjugate Vaccine (15-Valent)	NICE	Not available
	CDA	Not available
	HAS	Not applicable
	IQWIG	Not available
	PBAC	Not available

CONCLUSION STATEMENT - Pneumococcal Conjugate Vaccine (15-Valent)

Vaxneuvance® is a vaccine indicated for active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in individuals 6 weeks of age and older. It is administered intramuscularly as a single dose in individuals aged 18 years and older. The use of Vaxneuvance® is limited by its heightened risk of developing arthralgia, myalgia, and urticaria.

2.1.1.2 Prevnar 20® (Pneumococcal 20-valent Conjugate Vaccine)

Information on the vaccine are detailed below[36,37]:

Table 28. Prevnar 20® Drug Information

SCIENTIFIC NAME Pneumococcal 20-valent Conjugate Vaccine	
SFDA Classification	Prescription
SFDA Approval	Yes
US FDA	Yes
EMA	Yes
MHRA	Yes
PMDA	Yes
Indication (ICD-10)	B95.3
Drug Class	Vaccine
Drug Sub-class	Vaccine, Inactivated (Bacterial)
ATC Code	J07AL02
Pharmacological Class (ASHP)	80:12 - Vaccines
DRUG INFORMATION	
Dosage Form	Suspension for injection
Route of Administration	Intramuscular use
Dose (Adult) [DDD]*	0.5 mL as a single dose
Maximum Daily Dose Adults*	N/A
Adjustment	There are no dosage adjustments provided in the manufacturer's labeling.
Prescribing edits*	QL, PE
AGE (Age Edit)	N/A
CU (Concurrent Use Edit)	N/A
G (Gender Edit)	N/A
MD (Physician Specialty Edit)	N/A
PA (Prior Authorization)	N/A
QL (Quantity Limit)	Single dose
ST (Step Therapy)	N/A
EU (Emergency Use Only)	N/A
PE (Protocol Edit)	0.5 mL as a single dose
SAFETY	

Main Adverse Drug Reactions (Most common and most serious)	**Most common:** Erythema at injection site, pain at injection site, swelling at injection site. **Most serious:** Fatigue, headache, arthralgia, myalgia and fever.
Drug Interactions*	**Category X:** Atidarsagene Autotemcel Dinutuximab Beta Elivaldogene Autotemcel
Special Population	**Altered immunocompetence:** Consider deferring immunization during periods of severe immunosuppression (e.g., patients receiving chemo-/radiation therapy or other immunosuppressive therapy including high-dose corticosteroids); may have a reduced response to vaccination. Non-live vaccines should be administered ≥ 2 weeks prior to planned immunosuppression when feasible; non-live vaccines administered during chemotherapy should be readministered after immune competence is regained. **Older adult:** Antibody responses were lower in adults ≥ 70 years of age compared to adults 18 to 64 years of age.
Pregnancy	Although specific recommendations for vaccination of pregnant patients is not available, pneumococcal vaccines may be administered during pregnancy in persons at increased risk of severe disease due to underlying medical conditions.
Lactation	According to the manufacturer, the decision to breastfeed during therapy should consider the risk of infant

	exposure, the benefits of breastfeeding to the infant, and the benefits of treatment to the mother.
Contraindications	Severe allergic reaction (e.g., anaphylaxis) to pneumococcal conjugate vaccine, any component of the formulation, or any diphtheria toxoid-containing vaccine.
Monitoring Requirements	Monitor for anaphylaxis and syncope for 15 minutes following administration. If seizure-like activity associated with syncope occurs, maintain patient in supine or Trendelenburg position to reestablish adequate cerebral perfusion.
Precautions	**Shoulder injury related to vaccine administration:** Vaccine administration that is too high on the upper arm may cause shoulder injury (e.g., shoulder bursitis, tendinitis) resulting in shoulder pain and reduced range of motion following injection. Use proper injection technique for vaccines administered in the deltoid muscle (e.g., injecting in the central, thickest part of the muscle) to reduce the risk of shoulder injury related to vaccine administration. **Syncope:** Syncope has been reported with use of injectable vaccines and may result in serious secondary injury (e.g., skull fracture, cerebral hemorrhage); typically reported in adolescents and young adults and within 15 minutes after vaccination. Procedures should be in place to avoid injuries from falling and to restore cerebral perfusion if syncope occurs. **Acute illness:** The decision to administer or delay vaccination because of current or recent febrile illness depends on the severity of symptoms and the etiology of the disease. Defer

	administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever). **Bleeding disorders:** Use with caution in patients with bleeding disorders (including thrombocytopenia); bleeding/hematoma may occur from IM administration; if the patient receives antihemophilia or other similar therapy, IM injection can be scheduled shortly after such therapy is administered. **Vaccines:** In order to maximize vaccination rates, the Advisory Committee on Immunization Practices recommends simultaneous administration (ie, > 1 vaccine on the same day at different anatomic sites) of all age-appropriate vaccines (live or non-live) for which a person is eligible at a single visit, unless contraindications exist. **Polysorbate 80:** Some dosage forms may contain polysorbate 80 (also known as Tweens). Hypersensitivity reactions, usually a delayed reaction, have been reported following exposure to pharmaceutical products containing polysorbate 80 in certain individuals. **Antipyretics:** Antipyretics have not been shown to prevent febrile seizures; antipyretics may be used to treat fever or discomfort following vaccination. **Appropriate use:** Specific recommendations for use of vaccines in immunocompromised patients with asplenia, cancer, HIV infection, cerebrospinal fluid leaks, cochlear implants, hematopoietic stem cell transplant (prior to or after), sickle cell

	disease, solid organ transplant (prior to or after), or those receiving immunosuppressive therapy for chronic conditions are available from the Infectious Diseases Society of America. **Effective immunity:** Vaccination may not result in effective immunity in all patients. Response depends upon multiple factors (e.g., type of vaccine, age of patient) and may be improved by administering the vaccine at the recommended dose, route, and interval. Vaccines may not be effective if administered during periods of altered immune competence.
Black Box Warning	N/A
REMS*	N/A

HEALTH TECHNOLOGY ASSESSMENT (HTA)

The table below lists the HTA reviews and recommendations of Adult Immunization vaccines by the following agencies/institutes/authorities: National Institute for Health and Care Excellence (NICE), Canada's Drug Agency (CDA), Haute Autorité de Santé (HAS), Institute for Quality and Efficiency in Health Care (IQWIG), and Pharmaceutical Benefits Advisory Committee (PBAC) as applicable. **The recommendations below are for Pneumococcal 20-valent Conjugate Vaccine.**

Table 29. Prevnar 20® HTA Analysis

MEDICATION	AGENCY	DATE – HTA RECOMMENDATION
Pneumococcal 20-valent Conjugate Vaccine	NICE	N/A
	CDA[38]	**Requires further study – September 2024** At the time of the review, the National Advisory Committee on Immunization recommended adults at higher risk of Invasive Pneumococcal Disease receive a single dose of PCV20, or, if PCV20 is unavailable, a single dose of PCV15 followed by a single dose of PPSV23.
	HAS[19]	**Positive Recommendation – November 9, 2023**

		Favorable opinion on reimbursement in active immunization for the prevention of invasive diseases and pneumonia caused by *Streptococcus pneumoniae* in persons aged 18 years and over.
	IQWIG	N/A
	PBAC[20]	**Positive Recommendation – November 2022** The PBAC recommended in November 2022 that 20vPCV be a designated vaccine for the purposes of the *National Health Act 1953*, for the prevention of pneumococcal disease in individuals with a National Immunization Program-funded risk condition aged ≥ 18 years, non-Indigenous adults aged ≥ 70 years and Aboriginal and Torres Strait Islander adults aged ≥ 25 years.

CONCLUSION STATEMENT - Pneumococcal 20-valent Conjugate Vaccine

The ACIP recommends routine pneumococcal vaccination in adults aged 19 to 64 years of age with any of the following underlying medical conditions or risk factors: Alcohol use disorder, chronic heart disease, chronic liver disease, chronic lung disease, cigarette smoking, diabetes mellitus, cochlear implant, cerebrospinal fluid leaks, immunocompromising conditions and in adults ≥ 65 years of age. It is given as a 0.5ml intramuscular single dose. HAS and PBAC have backed the reimbursement of PCV-20. Its use is limited by the heightened risk of developing fatigue, headache, arthralgia, myalgia and fever.

2.1.2 Respiratory Syncytial Virus Vaccines

2.1.2.1 Arexvy® (Respiratory Syncytial Virus Vaccine, Adjuvanted)

Information on the vaccine are detailed below[36,37]:

Table 30. Arexvy® Drug Information

SCIENTIFIC NAME **Respiratory Syncytial Virus Vaccine, Adjuvanted**	
SFDA Classification	Prescription
SFDA Approval	Yes

US FDA	Yes
EMA	Yes
MHRA	Yes
PMDA	Yes
Indication (ICD-10)	Z23, Z24, Z25, Z26, Z27
Drug Class	Vaccine
Drug Sub-class	Vaccine, Recombinant, Adjuvanted
ATC Code	J07BX05
Pharmacological Class (ASHP)	80:12 - Vaccines
DRUG INFORMATION	
Dosage Form	Powder and suspension for suspension for injection
Route of Administration	Intramuscular use
Dose (Adult) [DDD]*	Adults 60 to 74 years of age who are at increased risk of severe RSV disease: 0.5 mL as a single dose **Note:** Persons who have previously received RSV vaccination are NOT recommended to receive another dose.
Maximum Daily Dose Adults*	N/A
Adjustment	There are no dosage adjustments provided in the manufacturer's labeling.
Prescribing edits*	AGE, QL, PE
AGE (Age Edit)	This vaccine is not approved for use in patients < 60 years of age.
CU (Concurrent Use Edit)	N/A
G (Gender Edit)	N/A
MD (Physician Specialty Edit)	N/A
PA (Prior Authorization)	N/A
QL (Quantity Limit)	Single dose
ST (Step Therapy)	N/A
EU (Emergency Use Only)	N/A
PE (Protocol Edit)	0.5 mL as a single dose intramuscularly
SAFETY	
Main Adverse Drug Reactions (Most common and most serious)	**Most serious:** Arthralgia, fever, Guillain Barre Syndrome (Post-marketing finding).

	Most common: Erythema at injection site, pain at injection site, fatigue, myalgia.
Drug Interactions*	**Category X:** Atidarsagene Autotemcel Dinutuximab Beta Elivaldogene Autotemcel
Special Population	**Altered immunocompetence:** Postpone vaccination during periods of severe immunosuppression (e.g., patients receiving chemo/radiation therapy or other immunosuppressive therapy [including high-dose corticosteroids]) if appropriate; may have a reduced response to vaccination. In general, household and close contacts of persons with altered immunocompetence may receive all age-appropriate vaccines. Nonlive vaccines should be administered ≥ 2 weeks prior to planned immunosuppression when feasible; nonlive vaccines administered during chemotherapy should be readministered after immune competence is regained.
Pregnancy	This vaccine is not approved for use in patients < 50 years of age. Arexvy (respiratory syncytial virus [recombinant, adjuvanted]) is not approved for use during pregnancy. Pregnant patients administered Arexvy vaccine in error should not be given a dose of Abrysvo (respiratory syncytial virus vaccine [recombinant]).
Lactation	This vaccine is not approved for use in patients < 50 years of age.

	According to the manufacturer, the decision to breastfeed following vaccination should consider the risk of infant exposure, the benefits of breastfeeding to the infant, and the benefits of treatment to the mother.
Contraindications	Severe hypersensitivity (e.g., anaphylaxis) to respiratory syncytial virus vaccine or any component of the formulation.
Monitoring Requirements	Monitor for hypersensitivity and syncope for 15 minutes following administration. If seizure-like activity associated with syncope occurs, maintain patient in supine or Trendelenburg position to reestablish adequate cerebral perfusion.
Precautions	**Anaphylactoid/hypersensitivity reactions:** Immediate treatment (including epinephrine 1 mg/mL) for anaphylactoid and/or hypersensitivity reactions should be available during vaccine use. **Inflammatory neurologic events:** Rare reports of Guillain-Barré syndrome and acute disseminated encephalomyelitis coadministered with Fluarix Quadrivalent vaccine). **Shoulder injury related to vaccine administration:** Vaccine administration that is too high on the upper arm may cause shoulder injury (e.g., shoulder bursitis, tendinopathy) resulting in shoulder pain and reduced range of motion following injection. Use proper injection technique for vaccines administered in the deltoid muscle (e.g., injecting in the central, thickest part of the muscle) to reduce the risk of

	shoulder injury related to vaccine administration. **Syncope:** Syncope has been reported with use of injectable vaccines and may result in serious secondary injury (e.g., skull fracture, cerebral hemorrhage); typically reported in adolescents and young adults and within 15 minutes after vaccination. Procedures should be in place to avoid injuries from falling and to restore cerebral perfusion if syncope occurs. **Acute illness:** The decision to administer or delay vaccination because of current or recent febrile illness depends on the severity of symptoms and the etiology of the disease. Postpone administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever). **Bleeding disorders:** Use with caution in patients with bleeding disorders (including thrombocytopenia); bleeding/hematoma may occur from IM administration; if the patient receives antihemophilia or other similar therapy, IM injection can be scheduled shortly after such therapy is administered. **Anticoagulant therapy:** Use with caution in patients receiving anticoagulant therapy; bleeding/hematoma may occur from IM administration.

	Vaccines: In order to maximize vaccination rates, the Advisory Committee on Immunization Practices recommends simultaneous administration (ie, > 1 vaccine on the same day at different anatomic sites) of all age-appropriate vaccines (live or nonlive) for which a person is eligible at a single visit, unless contraindications exist. **Antipyretics:** Antipyretics have not been shown to prevent febrile seizures; antipyretics may be used to treat fever or discomfort following vaccination. **Effective immunity:** Vaccination may not result in effective immunity in all patients. Response depends upon multiple factors (e.g., type of vaccine, age of patient) and is improved by administering the vaccine at the recommended dose, route, and interval.
Black Box Warning	N/A
REMS*	N/A

HEALTH TECHNOLOGY ASSESSMENT (HTA)

The table below lists the HTA reviews and recommendations of Adult Immunization vaccines by the following agencies/institutes/authorities: National Institute for Health and Care Excellence (NICE), Canada's Drug Agency (CDA), Haute Autorité de Santé (HAS), Institute for Quality and Efficiency in Health Care (IQWIG), and Pharmaceutical Benefits Advisory Committee (PBAC) as applicable. **The recommendations below are for Respiratory Syncytial Virus Vaccine, Adjuvanted.**

Table 31. Arexvy® HTA Analysis

MEDICATION	AGENCY	DATE – HTA RECOMMENDATION
Respiratory Syncytial Virus	NICE	N/A
	CDA[13]	**Generalizability is limited; further studies required – February 2024:**

Vaccine, Adjuvanted		The results of all publications found that RSVPreF3 (Arexvy) and RSVpreF (Abrysvo) were more costly and more effective than no intervention for RSV-associated disease. All publications reported that vaccinating older adults against RSV disease was potentially cost-effective. All publications noted that the cost-effectiveness was dependent on vaccine cost, vaccine efficacy, the waning of vaccine protection, RSV hospitalization incidence, health care unit costs, and respective regional willingness-to-pay thresholds.
	HAS[11]	**Positive Recommendation – September 2024** Favorable opinion on reimbursement in active immunization for the prevention of lower respiratory tract disease caused by RSV namely in subjects aged 75 and over and subjects aged 65 and over with chronic respiratory (particularly COPD) or cardiac (particularly heart failure) pathologies likely to decompensate during an RSV infection.
	IQWIG	N/A
	PBAC[12]	**Negative Recommendation – July 2024:** The PBAC did not recommend that respiratory syncytial virus vaccine (Arexvy®, RSVpreF3 OA) be a designated vaccine for the purposes of the National Health Act 1953 for the prevention of lower respiratory tract illness caused by respiratory syncytial virus (RSV).

CONCLUSION STATEMENT - Respiratory Syncytial Virus Vaccine, Adjuvanted

The Advisory Committee on Immunization Practices (ACIP) recommends vaccination with Arexvy® in persons ≥ 75 years of age and in persons 60 to 74 years of age who are at increased risk of severe RSV disease. Arexvy is given as 0.5 mL

single dose intramuscularly. CADTH has partially backed Arexvy for its cost-effectiveness; however, further study is required to prove its cost-effectiveness. Its use is limited by the occurrence of arthralgia, fever, or rarely Guillain Barre Syndrome.

2.1.2.2 Abrysvo® (Recombinant Respiratory Syncytial Virus Vaccine (RSVPreF))

Information on the vaccine are detailed below[36,37]:

Table 32. Abrysvo® Drug Information

SCIENTIFIC NAME **Recombinant respiratory syncytial virus vaccine (RSVPreF)**	
SFDA Classification	Prescription
SFDA Approval	Yes
US FDA	Yes
EMA	Yes
MHRA	Yes
PMDA	Yes
Indication (ICD-10)	Z23, Z24, Z25, Z26, Z27
Drug Class	Vaccine
Drug Sub-class	Vaccine, Recombinant
ATC Code	J07BX05
Pharmacological Class (ASHP)	80:12 - Vaccines
DRUG INFORMATION	
Dosage Form	Powder and solvent for solution for injection
Route of Administration	Intramuscular use
Dose (Adult) [DDD]*	0.5 mL as a single dose
Maximum Daily Dose Adults*	N/A
Adjustment	There are no dosage adjustments provided in the manufacturer's labeling.
Prescribing edits*	AGE, QL, PE
AGE (Age Edit)	Abrysvo is administered to those aged 60 or older and to adults aged 18–59 who are at high risk for severe RSV infection.
CU (Concurrent Use Edit)	N/A
G (Gender Edit)	N/A

MD (Physician Specialty Edit)	N/A
PA (Prior Authorization)	N/A
QL (Quantity Limit)	Single dose
ST (Step Therapy)	N/A
EU (Emergency Use Only)	N/A
PE (Protocol Edit)	Given as a 0.5ml intramuscular dose
SAFETY	
Main Adverse Drug Reactions (Most common and most serious)	**Most serious:** Hypersensitivity reaction, arthralgia, myalgia. **Most common:** Pain at the injection site headache, fatigue.
Drug Interactions*	**Category X:** Atidarsagene Autotemcel Dinutuximab Beta Elivaldogene Autotemcel
Special Population	Postpone vaccination during periods of severe immunosuppression (e.g., patients receiving chemo/radiation therapy or other immunosuppressive therapy [including high-dose corticosteroids]) if appropriate; may have a reduced response to vaccination. Nonlive vaccines should be administered ≥ 2 weeks prior to planned immunosuppression when feasible; nonlive vaccines administered during chemotherapy should be readministered after immune competence is regained.
Pregnancy	Abrysvo (respiratory syncytial virus vaccine [recombinant]) is the only RSV vaccine approved for use during pregnancy. Pregnant patients administered Arexvy (respiratory syncytial virus [recombinant, adjuvanted]) vaccine in error should not be given a dose of Abrysvo.

Lactation	According to the manufacturer, the decision to breastfeed following vaccination should consider the risk of infant exposure, the benefits of breastfeeding to the infant, and the benefits of treatment.
Contraindications	Severe hypersensitivity (e.g., anaphylaxis) to respiratory syncytial virus vaccine (recombinant) or to any component of the formulation.
Monitoring Requirements	Monitor for hypersensitivity and syncope for 15 minutes following administration. If seizure-like activity associated with syncope occurs, maintain patient in supine or Trendelenburg position to reestablish adequate cerebral perfusion.
Precautions	**Anaphylactoid/hypersensitivity reactions:** Immediate treatment (including injectable epinephrine 1 mg/mL) for anaphylactoid and/or hypersensitivity reactions should be available during vaccine use. **Inflammatory neurologic events:** There have been rare reports of Guillain-Barré syndrome, Miller Fisher syndrome, and undifferentiated motor-sensory axonal polyneuropathy with worsening of preexisting symptoms. **Shoulder injury related to vaccine administration:** Vaccine administration that is too high on the upper arm may cause shoulder injury (e.g., shoulder bursitis, tendinopathy) resulting in shoulder pain and reduced range of motion following injection. Use proper injection technique for vaccines administered in the deltoid muscle (e.g., injecting in the central, thickest part of

	the muscle) to reduce the risk of shoulder injury related to vaccine administration. **Syncope:** Syncope has been reported with use of injectable vaccines and may result in serious secondary injury (e.g., skull fracture, cerebral hemorrhage); typically reported in adolescents and young adults and within 15 minutes after vaccination. Procedures should be in place to avoid injuries from falling and to restore cerebral perfusion if syncope occurs. **Acute illness:** Postpone administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever). **Bleeding disorders:** Use with caution in patients with bleeding disorders (including thrombocytopenia); bleeding/hematoma may occur from IM administration; if the patient receives antihemophilia or other similar therapy, IM injection can be scheduled shortly after such therapy is administered. **Anticoagulant therapy:** Use with caution in patients receiving anticoagulant therapy; bleeding/hematoma may occur from IM administration. **Vaccines:** In order to maximize vaccination rates, the Advisory Committee on Immunization Practices recommends simultaneous

	administration (ie, > 1 vaccine on the same day at different anatomic sites) of all age-appropriate vaccines (live or nonlive) for which a person is eligible at a single visit, unless contraindications exist. **Polysorbate 80:** Some dosage forms may contain polysorbate 80 (also known as Tweens). Hypersensitivity reactions, usually a delayed reaction, have been reported following exposure to pharmaceutical products containing polysorbate 80 in certain individuals. **Antipyretics:** Antipyretics have not been shown to prevent febrile seizures; antipyretics may be used to treat fever or discomfort following vaccination. **Effective immunity:** Vaccination may not result in effective immunity in all patients. Response depends upon multiple factors (e.g., type of vaccine, age of patient) and is improved by administering the vaccine at the recommended dose, route, and interval.
Black Box Warning	N/A
REMS*	N/A

HEALTH TECHNOLOGY ASSESSMENT (HTA)

The table below lists the HTA reviews and recommendations of Adult Immunization vaccines by the following agencies/institutes/authorities: National Institute for Health and Care Excellence (NICE), Canada's Drug Agency (CDA), Haute Autorité de Santé (HAS), Institute for Quality and Efficiency in Health Care (IQWIG), and Pharmaceutical Benefits Advisory Committee (PBAC) as applicable. **The recommendations below are for Recombinant respiratory syncytial virus vaccine (RSVPreF).**

Table 33. Abrysvo® HTA Analysis

MEDICATION	AGENCY	DATE – HTA RECOMMENDATION
Recombinant respiratory syncytial virus vaccine (RSVPreF)	NICE	N/A
	CDA[16]	**Pregnancy-specific Vaccination: Inconclusive – August 2023** There is a lack of evidence on outcomes — thus cost-effectiveness — for the persons who are pregnant. RSV immunization during pregnancy was estimated to become cost-effective when its acquisition cost per dose was 2 to 5 times lower than that of the long-acting mAb.
	HAS[15]	**Positive Recommendation – September 6, 2024** Favorable opinion on reimbursement in active immunization for the prevention of lower respiratory tract disease caused by RSV according to the current HAS vaccination recommendations of June 27, 2024, namely in subjects aged 75 and over and subjects aged 65 and over with chronic respiratory (particularly COPD) or cardiac (particularly heart failure) pathologies likely to decompensate during an RSV infection.
	IQWIG	N/A
	PBAC[17]	**Pregnancy-specific Vaccination: Negative Recommendation – May 2024** The PBAC did not recommend recombinant syncytial pre-fusion F protein vaccine (RSVpreF) for the prevention of lower respiratory tract illness (LRTI) caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age by active immunization of pregnant women.

CONCLUSION STATEMENT - Recombinant respiratory syncytial virus vaccine (RSVPreF)

Abrysvo® is recommended for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in persons ≥ 60 years of age and in persons 18 to 59 years of age who are at increased risk of LRTD caused by RSV. Additionally, it is the only safe RSV vaccine for pregnant patients and is recommended to be given at 32 through 36 weeks' gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age. It is given as 0.5ml single dose intramuscularly. Its reimbursement is backed by HAS and its use is limited by a heightened risk of hypersensitivity reactions, arthralgia, and myalgia.

2.1.2 Human Papillomavirus Vaccine

2.1.3.1 Gardasil® 9 (Human Papillomavirus 9-Valent Vaccine, Recombinant)

Information on the vaccine are detailed below[36,37]:

Table 34. Gardasil® 9 Drug Information

SCIENTIFIC NAME **Human Papillomavirus 9-valent Vaccine, Recombinant**	
SFDA Classification	Prescription
SFDA Approval	Yes
US FDA	Yes
EMA	Yes
MHRA	Yes
PMDA	Yes
Indication (ICD-10)	Z23, Z24, Z25, Z26, Z27
Drug Class	Vaccine
Drug Sub-class	Vaccine, Inactivated (Viral); Vaccine, Recombinant
ATC Code	J07BM03
Pharmacological Class (ASHP)	80:12 - Vaccines
DRUG INFORMATION	
Dosage Form	Suspension for injection
Route of Administration	Intramuscular use
Dose (Adult) [DDD]*	Adults ≤ 45 years of age: 3-dose series: 0.5 mL at 0, 2, and 6 months. ***Have not received any doses*:**

	3-dose series: 0.5 mL at 0, 1 to 2, and 6 months. There should be a 4-week minimum interval between the first and second dose; a 12-week minimum interval between the second and third dose; a 5-month minimum interval between the first and third dose. ***Partially vaccinated, first dose before 15 years of age*:** If 2 doses administered at least 5 months apart: No more doses needed. If only a single dose or if doses < 5 months apart: Administer one additional 0.5 mL dose. ***Partially vaccinated, first dose at 15 years of age or later*:** Complete 3-dose series: There should be a 4-week minimum interval between the first and second dose; a 12-week minimum interval between the second and third dose; a 5-month minimum interval between the first and third dose.
Maximum Daily Dose Adults*	N/A
Adjustment	There are no dosage adjustments provided in the manufacturer's labeling.
Prescribing edits*	AGE, PE
AGE (Age Edit)	GARDASIL 9 is a vaccine indicated in girls and women 9 through 45 years of age.
CU (Concurrent Use Edit)	N/A
G (Gender Edit)	N/A (May also be given to men)
MD (Physician Specialty Edit)	N/A
PA (Prior Authorization)	N/A
QL (Quantity Limit)	N/A
ST (Step Therapy)	N/A
EU (Emergency Use Only)	N/A

PE (Protocol Edit)	3-dose series: 0.5 mL at 0, 1 to 2, and 6 months OR 2 dose series; separated by 5 months.
SAFETY	
Main Adverse Drug Reactions (Most common and most serious)	**Most common:** Erythema at injection site, pain at injection site, swelling at injection site, headache. **Most serious:** Myalgia, fever, oropharyngeal pain and dizziness.
Drug Interactions*	**Category X:** Atidarsagene Autotemcel Dinutuximab Beta Elivaldogene Autotemcel
Special Population	**Altered immunocompetence:** Postpone vaccination during periods of severe immunosuppression (e.g., patients receiving chemo/radiation therapy or other immunosuppressive therapy [including high-dose corticosteroids]) if appropriate; may have a reduced response to vaccination. In general, household and close contacts of persons with altered immunocompetence may receive all age-appropriate vaccines. Nonlive vaccines should be administered ≥ 2 weeks prior to planned immunosuppression when feasible; nonlive vaccines administered during chemotherapy should be readministered after immune competence is regained.
Pregnancy	Administration of the vaccine during pregnancy is not recommended. The vaccine series (or completion of the series) should be delayed until pregnancy is completed.
Lactation	Maternal vaccination is not a contraindication to breastfeeding; the

	papillomavirus vaccine may be administered to breastfeeding patients. Non-live vaccines have not been shown to affect the safety of the breastfed infant or mother.
Contraindications	Hypersensitivity, including severe allergic reactions to yeast (a vaccine component), or after a previous dose of this vaccine or human papillomavirus (types 6, 11, 16, 18) vaccine (recombinant).
Monitoring Requirements	Screening for human papillomavirus is not required prior to vaccination. Monitor for hypersensitivity and syncope for 15 minutes following administration. If seizure-like activity associated with syncope occurs, maintain patient in supine or Trendelenburg position to reestablish adequate cerebral perfusion. Continue recommended anal cancer screening. Females: Gynecologic screening exam, papillomavirus test; screening for cervical cancer should continue per current guidelines following vaccination.
Precautions	**Anaphylactoid/hypersensitivity reactions:** Immediate treatment (including epinephrine 1 mg/mL) for anaphylactoid and/or hypersensitivity reactions should be available during vaccine use. **Shoulder injury related to vaccine administration:** Vaccine administration that is too high on the upper arm may cause shoulder injury (e.g., shoulder bursitis or tendinitis) resulting in shoulder pain and reduced range of motion following injection. Use proper injection technique for vaccines administered in the deltoid muscle (e.g., injecting in the central, thickest part of

	the muscle) to reduce the risk of shoulder injury related to vaccine administration. **Syncope:** Syncope has been reported with use of injectable vaccines and may result in serious secondary injury (e.g., skull fracture, cerebral hemorrhage); typically reported in adolescents and young adults and within 15 minutes after vaccination. Procedures should be in place to avoid injuries from falling and to restore cerebral perfusion if syncope occurs. **Acute illness:** Postpone administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever). **Bleeding disorders:** Use with caution in patients with a history of bleeding disorders (including thrombocytopenia); bleeding/hematoma may occur from IM administration; if the patient receives antihemophilia or other similar therapy, IM injection can be scheduled shortly after such therapy is administered. **Human papillomavirus infection:** There is no evidence that individuals already infected with human papillomavirus (HPV) will be protected; those already infected with 1 or more HPV types were protected from disease caused by the remaining HPV types. Not for the treatment of active disease; will not protect against diseases not caused by HPV vaccine types not included in the vaccine. Does not eliminate the necessity for recommended cervical or anal cancer screenings.

	Vaccines: In order to maximize vaccination rates, the ACIP recommends simultaneous administration of all age-appropriate vaccines (live or nonlive) for which a person is eligible at a single visit, unless contraindications exist. **Polysorbate 80:** Some dosage forms may contain polysorbate 80 (also known as Tweens). Hypersensitivity reactions, usually a delayed reaction, have been reported following exposure to pharmaceutical products containing polysorbate 80 in certain individuals. **Previously vaccinated with Gardasil (quadrivalent):** Per the ACIP, if the provider does not have available or does not know the HPV product used previously, any gender appropriate product can be used to complete the series **Yeast:** Product may contain yeast. **Appropriate use:** Use of this vaccine for specific medical and/or other indications (e.g., immunocompromising conditions, hepatic or kidney disease, diabetes) is also addressed in the annual ACIP Recommended Immunization Schedules (refer to CDC schedule for detailed information). Specific recommendations for vaccination in immunocompromised patients with asplenia, cancer, HIV infection, cerebrospinal fluid leaks, cochlear implants, hematopoietic stem cell transplant (prior to or after), sickle cell disease, solid organ transplant (prior to or after), or those receiving immunosuppressive therapy for chronic conditions are available from the IDSA.

	Effective immunity: Vaccination may not result in effective immunity in all patients. Response depends upon multiple factors (e.g., type of vaccine, age of patient) and may be improved by administering the vaccine at the recommended dose, route, and interval. Vaccination is safe for individuals 27 to 45 years of age; however, consider decreased effectiveness and potential for lower cancer prevention in these older ages. **Maximum efficacy:** The entire series should be completed for maximum efficacy.
Black Box Warning	N/A
REMS*	N/A

HEALTH TECHNOLOGY ASSESSMENT (HTA)

The table below lists the HTA reviews and recommendations of Adult Immunization vaccines by the following agencies/institutes/authorities: National Institute for Health and Care Excellence (NICE), Canada's Drug Agency (CDA), Haute Autorité de Santé (HAS), Institute for Quality and Efficiency in Health Care (IQWIG), and Pharmaceutical Benefits Advisory Committee (PBAC) as applicable. **The recommendations below are for Human Papillomavirus 9-valent Vaccine, Recombinant.**

Table 35. Gardasil® 9 HTA Analysis

MEDICATION	AGENCY	DATE – HTA RECOMMENDATION
Human Papillomavirus 9-valent Vaccine, Recombinant	NICE	N/A
	CDA	N/A
	HAS[21]	**Positive Recommendation – March 5, 2020** Favorable opinion on reimbursement in the prevention of infections and lesions due to certain oncogenic types of Human Papillomavirus (HPV), in girls and boys, according to the terms defined by the vaccination schedule in force.

		Place in therapeutic strategy: • All girls and boys aged 11 to 14 inclusive, **with a possible catch-up for all adolescents and young adults (men and women) aged 15 to 19 inclusive**; • Men who have sex with men (MSM) up to the age of 26
	IQWIG	N/A
	PBAC[22]	**Conditional Positive Recommendation – December 2022** The PBAC recommended that the National Immunisation Program (NIP) listing of 9vHPV vaccine be changed from two doses to one dose for the adolescent vaccination program and that the upper age limit for catch up vaccination be updated from 20 years to 25 years.

CONCLUSION STATEMENT - Human Papillomavirus 9-valent Vaccine, Recombinant

The Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination for females and males 11 to 12 years of age; for patients with any history of sexual abuse or assault, vaccination should be started at 9 years of age. Catch-up vaccination is recommended for all persons through 26 years of age. Shared clinical decision-making regarding catch-up HPV vaccination is recommended for some adults 27 to 45 years of age. The vaccine is given intramuscularly either as a 2-dose (2 doses administered 5 months apart) or a 3-dose series (0.5 mL at 0, 2, and 6 months). Both HAS and PBAC have backed the reimbursement of the Human Papillomavirus 9-valent Vaccine, Recombinant. Its use is limited by the potential onset of myalgia, fever, oropharyngeal pain and dizziness.

2.2 Drug Modifications

The following modifications and adjustments have been implemented since the 2020 report:

- An **AGE** prescribing edit was **added** for “MONOVALENT INACTIVATED SPILIT VIRION AH 1N1,MONOVALENT INACTIVATED SPILIT VIRION AH 3N2,MONOVALENT INACTIVATED SPILIT VIRION B STRAIN VICTORIA LINEAGE,MONOVALENT INACTIVATED SPILIT VIRION B STRAIN YAMAGATE

LINEAGE" and "A/Victoria/2570/2019 (H1N1)pdm09- like virus, A/Darwin/9/2021 (H3N2)-like virus,B/Austria/1359417/2021 (B/Victoria lineage)-like virus": "Safety and effectiveness of FLUARIX QUADRIVALENT in children younger than 6 months have not been established."

- A **PE** prescribing edit was **added** for "MONOVALENT INACTIVATED SPILIT VIRION AH 1N1,MONOVALENT INACTIVATED SPILIT VIRION AH 3N2,MONOVALENT INACTIVATED SPILIT VIRION B STRAIN VICTORIA LINEAGE,MONOVALENT INACTIVATED SPILIT VIRION B STRAIN YAMAGATE LINEAGE" and "A/Victoria/2570/2019 (H1N1)pdm09- like virus, A/Darwin/9/2021 (H3N2)-like virus,B/Austria/1359417/2021 (B/Victoria lineage)-like virus": "Safety and effectiveness of FLUARIX QUADRIVALENT in children younger than 6 months have not been established.": "Influenza Vaccine is to be administered annually in patients aged 6 months and older."
- The **MD** prescribing edit was **removed** for "MONOVALENT INACTIVATED SPILIT VIRION AH 1N1,MONOVALENT INACTIVATED SPILIT VIRION AH 3N2,MONOVALENT INACTIVATED SPILIT VIRION B STRAIN VICTORIA LINEAGE,MONOVALENT INACTIVATED SPILIT VIRION B STRAIN YAMAGATE LINEAGE" and "A/Victoria/2570/2019 (H1N1)pdm09- like virus, A/Darwin/9/2021 (H3N2)-like virus,B/Austria/1359417/2021 (B/Victoria lineage)-like virus"
- An **AGE** prescribing edit and a **PE** prescribing edit were **added** and **MD** was **removed** for "DIPHTHERIA TOXOID,TETANUS TOXOID,Haemagglutinin,PERTACTIN,ACELLULAR PERTUSSIS": "AGE: DIPHTHERIA TOXOID,TETANUS TOXOID,Haemagglutinin,PERTACTIN,ACELLULAR PERTUSSIS is not indicated for use in children aged younger than 10 years. Safety and effectiveness of DIPHTHERIA TOXOID,TETANUS TOXOID,Haemagglutinin,PERTACTIN,ACELLULAR PERTUSSIS in this age group have not been established. PE: If patient previously did not receive Tdap at or after age 11 years: 1 dose Tdap, then Td or Tdap every 10 years."
- For Hepatitis A vaccines: **PA** was **removed**, **AGE** was **added** "Hepatitis A vaccine is not indicated for immunization of persons below the age of 12 years." and **PE** was **added**: "2-dose series HepA (Havrix 6–12 months apart or Vaqta 6–18 months apart [minimum interval: 6 months]) or 3-dose series HepA-HepB (Twinrix at 0, 1, 6 months [minimum intervals: 4 weeks between doses 1 and 2/5 months between doses 2 and 3])"
- For HEPATITIS A VIRUS,HEPATITIS B VIRUS HBSAG SURFACE ANTIGEN: **PA** was **removed**, **PE and AGE** prescribing edits were **added**: "**AGE**: Safety and effectiveness in pediatric patients younger than 18 years have not been established. **PE**: For patients aged 19 through 59 years: 3-dose series HepA-HepB (Twinrix at 0, 1, 6 months [minimum intervals: dose 1 to dose 2: 4 weeks /

dose 2 to dose 3: 5 months]) OR 4-dose series HepA-HepB (Twinrix) accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months."

- The Gender prescribing edit was removed for the HPV vaccines. An AGE and PE prescribing edit were added: "AGE: Safety and effectiveness have not been established in pediatric patients below 9 years of age. PE: HPV vaccination recommended for all adults through age 26 years: 2- or 3-dose series depending on age at initial vaccination or condition. Age 27 through 45 years based on shared clinical - 2- or 3-dose."
- The **PA** prescribing edit was **removed** for the MMR vaccines. An **AGE** and **PE** prescribing edits were **added**; "AGE: M-M-R II vaccine is not approved for individuals less than 12 months of age. Safety and effectiveness of measles vaccine in infants below the age of 6 months have not been established. Safety and effectiveness of mumps and rubella vaccine in infants less than 12 months of age have not been established. PE: No evidence of immunity to measles, mumps, or rubella: 1 dose, Evidence of immunity: Born before 1957 (health care personnel, see below), documentation of receipt of MMR vaccine, laboratory evidence of immunity or disease (diagnosis of disease without laboratory confirmation is not evidence of immunity)."
- The **MD** prescribing edit was **removed** for meningococcal vaccines. **AGE** and **PE** prescribing edits were **added**; "AGE: Safety and effectiveness of meningococcal vaccine in children aged younger than 2 months have not been established. PE: In individuals aged 2 through 55 years, administer as a single dose. A single booster dose of MENVEO may be administered to individuals aged 15 through 55 years who are at continued risk for meningococcal disease if at least 4 years have elapsed since a prior dose of a meningococcal (serogroups A, C, Y, W-135) conjugate vaccine."
- The **PA** prescribing edits were **removed** for PPSV23. **AGE** and **PE** prescribing edits were **added**; "AGE: PPSV23 is not approved for use in children younger than 2 years of age. PE: For patients who never received any pneumococcal vaccine; For these adults, regardless of risk condition: Give 1 dose of PCV15 or PCV20. When PCV15 is used, it should be followed by a dose of PPSV23 at least 1 year later. The minimum interval (8 weeks) can be considered in adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak. For patients who have only taken PCV13; for these adults who have a risk condition other than an immunocompromising condition: Give 1 dose of PCV20 or PPSV23. The PPSV23 dose should be given at least 8 weeks after PCV13 for those with a cochlear implant or cerebrospinal fluid leak. The PPSV23 dose should be given at least 1 year after PCV13 for any of the other chronic health conditions. When PPSV23 is used, no additional pneumococcal

vaccines are recommended until at least age 65 years. For these adults who have an immunocompromising condition: Give 1 dose of PCV20 or PPSV23. For Patients who have Received PCV13 and 1 Dose of PPSV23: For these adults who have an immunocompromising condition: Give 1 dose of PCV20 or a second PPSV23 dose. The second dose of PPSV23 should be given at least 8 weeks after PCV13 and 5 years after PPSV23. No additional pneumococcal vaccines are recommended until at least age 65 years."

- For PCV13, the **PA** prescribing edit was **removed**. **AGE** and **PE** prescribing edits were **added**; "AGE: Safety and effectiveness of Prevnar 13 in children below the age of 6 weeks have not been established. PE: Adults 18 years and older: a single dose."
- For Varicella vaccines, the **PA** prescribing edit was **removed**. **AGE** and **PE** prescribing edits were **added**; "AGE: No clinical data are available on safety or efficacy of varicella vaccine in children less than 12 months of age. PE: No evidence of immunity to varicella: 2-dose series 4–8 weeks apart if previously did not receive varicella containing vaccine (VAR or MMRV [measles-mumps rubella- varicella vaccine] for children); if previously received 1 dose varicella-containing vaccine, 1 dose at least 4 weeks after first dose. Evidence of immunity: U.S.-born before 1980 (except for pregnant women and health care personnel), documentation of 2 doses varicella-containing vaccine at least 4 weeks apart, diagnosis or verification of history of varicella or herpes zoster by a health care provider, laboratory evidence of immunity or disease."

2.3 Delisting

The vaccines below are no longer SFDA registered, therefore, it is recommended to delist the following drugs from CHI formulary[36]:

Table 36. Delisted Drugs

Delisted Medications	Reason	Medication Status	Alternative
HAEMOPHILUS INFLUENZAE TYPE B (VAXEM Hib® and ACT-HIB®)	Withdrawn from SFDA	In 2017, GlaxoSmithKline (GSK) announced the discontinuation of the manufacture and supply of VAXEM Hib® worldwide as part of an ongoing process by GSK to optimize its	There are no alternative agents on the SFDA. *Haemophilus Influenzae* Type B only exists as a part of combination vaccinations.

		worldwide manufacturing footprint. ACT-HIB® is registered on the NUPCO list. ACT-HIB® is a vaccine indicated for the prevention of invasive disease caused by *Haemophilus influenzae* type b.	
INFLUENZA VACCINE (FLUARIX 15 MCG OF ECH INFUENZA STR.5 ML SYRINGE and INFLUENZA VACCINE SURFACE ANTIGEN NYMC X-181, NYMC X-187, AND NYMC BX-35)	Withdrawn from SFDA	There is no apparent reason for the withdrawal of the vaccines from the SFDA.	Alternatives include: • FLUARIX TETRA Suspension for Injection in Pre-filled Syringe® (MONOVALENT INACTIVATED SPILIT VIRION AH 1N1,MONOVALENT INACTIVATED SPILIT VIRION AH 3N2,MONOVALENT INACTIVATED SPILIT VIRION B STRAIN VICTORIA LINEAGE,MONOVALENT INACTIVATED SPILIT VIRION B STRAIN YAMAGATE LINEAGE) • Influvac Vaccine® (A/Victoria/2570/2019 (H1N1)pdm09- like virus,A/Darwin/9/2021 (H3N2)-like virus,B/Austria/1359417/2021 (B/Victoria lineage)-like virus) • Influvac Tetra® (A/Brisbane/02/2018

			(H1N1),A/Kansas/14/2017 (H3N2),B/Colorado/06/2017,B/Phuket/3073/2013) • VaxigripTetra® (INFLUENZA A VIRUS A/INDONESIA/5/2005 (H5N1) ANTIGEN (UV, FORMALDEHYDE INACTIVATED) & INFLUENZA VIRUS INACTIVATED SPLIT)
POLYSACCHARIDE OF NEISSERIA MENINGITIDIS GROUP A, POLYSACCHARIDE OF NEISSERIA MENINGITIDIS GROUP C (ARAMEN®,	Withdrawn from SFDA	There is no apparent reason for the withdrawal of the vaccine from the SFDA.	Alternatives include: • Menveo® (MENINGOCOCCAL GROUP A (NEISSERIA MENINGITIDIS) POLYSACCHARIDE VACCINE,MENINGOCOCCAL GROUP C (NEISSERIA MENINGITIDIS) POLYSACCHARIDE,MENINGOCOCCAL GROUP W (NEISSERIA MENINGITIDIS) POLYSACCHARIDE,MENINGOCOCCAL GROUP Y (NEISSERIA MENINGITIDIS) POLYSACCHARIDE) • Menactra® (MENINGOCOCCAL GROUP A (NEISSERIA MENINGITIDIS) POLYSACCHARIDE VACCINE,MENINGOCOCCAL GROUP C (NEISSERIA MENINGITIDIS) POLYSACCHARIDE,MENINGOCOCCAL GROUP

			W (NEISSERIA MENINGITIDIS) POLYSACCHARIDE,MENINGOCOCCAL GROUP Y (NEISSERIA MENINGITIDIS) POLYSACCHARIDE,DIPHTHERIA TOXOID) • Nimenrix® (TETANUS TOXOID,MENINGOCOCCAL GROUP A (NEISSERIA MENINGITIDIS) POLYSACCHARIDE VACCINE,MENINGOCOCCAL GROUP C (NEISSERIA MENINGITIDIS) POLYSACCHARIDE,MENINGOCOCCAL GROUP W (NEISSERIA MENINGITIDIS) POLYSACCHARIDE,MENINGOCOCCAL GROUP Y (NEISSERIA MENINGITIDIS) POLYSACCHARIDE)
messenger RNA (mRNA) (embedded in SM-102 lipid nanoparticles)	Withdrawn from SFDA	Moderna has scaled back manufacturing for the Spikevax COVID booster to cope with falling demand.	Alternatives on the SFDA Market: TOZINAMERAN

2.4 Other Drugs

The following vaccines discussed are newly approved vaccines which are FDA approved; however, they are **not yet SFDA registered**.

2.4.1 COVID-19 Vaccines

2.4.1.1 Nuvaxovid® and Covovax® – Novavax

The Novavax vaccine was granted approval by the FDA in 2022 and received conditional marketing authorization by the EMA in 2021. The FDA approved a 2023-2024 Novavax vaccine in October 2023 for ages 12 and older to target the SARS-CoV-2 XBB.1.5 strain. It is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older. The Novavax vaccine promotes active immunization against COVID-19 caused by SARS-CoV-2 virus. The vaccine contains a purified recombinant spike (S) antigen of the SARS-Co-V-2 virus. The vaccine then elicits an immune response to the S antigen, which contributes to protection against COVID-19 disease. It is given intramuscularly as 0.5 mL per dose for 2 doses administered 3 to 8 weeks apart.

2.4.2 Respiratory Syncytial Virus Vaccine

2.4.2.1 Mresvia® (Respiratory Syncytial Virus mRNA Vaccine)

Mresvia® was approved by the FDA on May 31st of 2024 and by the EMA on August 22nd of 2024. It is indicated to protect adults aged 60 years and older from lower respiratory tract disease caused by RSV infection. The Advisory Committee on Immunization Practices (ACIP) recommends vaccination in persons ≥ 75 years of age and in persons 60 to 74 years of age who are at increased risk of severe RSV disease. The approval was granted under a breakthrough therapy designation. It is given as a 0.5ml single dose, intramuscularly. Persons who have previously received RSV vaccination are not recommended to receive another dose.

2.4.3 Hepatitis B Virus Vaccines

2.4.3.1 PreHevbrio®

PreHevbrio® was approved by the FDA in November of 2021 and by the EMA in April of 2022. It is indicated for prevention of infection caused by all known subtypes of hepatitis B virus. PreHevbrio® is approved for use in adults 18 years of age and older. Hepatitis B vaccine (trivalent [recombinant]) is a noninfectious viral vaccine containing 3 hepatitis B surface antigens, which confers active immunity via formation of antihepatitis B antibodies. It is an injectable suspension, for intramuscular use supplied as a single-dose vial. A single dose of PreHevbrio® is 1.0 mL.

2.4.4 Meningococcal Vaccines

2.4.4.1 MenQuadfi®

MenQuadfi® was initially approved by the FDA and the EMA in 2020. It is indicated for active immunization for the prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W, and Y. MenQuadfi® is approved for use in individuals 2 years of age and older. It does not prevent N. meningitidis serogroup B disease. It induces immunity against meningococcal disease via the formation of bactericidal antibodies directed toward the polysaccharide capsular components of *Neisseria meningitidis* serogroups A, C, Y and W-135. It is given intramuscularly as a single dose of 0.5ml. A single dose of MenQuadfi® may be administered to individuals 13 years of age and older who are at continued risk for meningococcal disease if at least 3 years have elapsed since a prior dose of meningococcal (groups A, C, W, Y) conjugate vaccine. For those who have received a prior dose of meningococcal polysaccharide vaccine, a single dose of MenQuadfi® may be administered if at least 3 years have elapsed since a prior dose of meningococcal polysaccharide vaccine.

2.4.4.2 Penbraya®

Penbraya® was approved by the FDA in October of 2023. It is indicated for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroups A, B, C, W, and Y. Penbraya® is approved for use in individuals 10 through 25 years of age. Penbraya® is a pentavalent vaccine targeting meningococcal serogroups A, B, C, Y and W; it conveys active immunity via stimulation of production of endogenously produced antibodies. Protection against invasive meningococcal disease is conferred mainly by complement-mediated, antibody-dependent killing of *N meningitidis*. It is given intramuscularly as 2 doses (approximately 0.5 mL each) 6 months apart.

2.4.5 Pneumococcal Vaccines

2.4.5.1 Capvaxive® (Pneumococcal 21-Valent Conjugate Vaccine)

Capvaxive® was approved by the FDA on June 17th of 2024. It is indicated for the prevention of invasive pneumococcal disease and pneumococcal pneumonia in adults. It is given as a single dose of 0.5ml, intramuscularly. PCV21 includes 8 serotypes not included in PCV15 or PCV20; however, it does not include serotype 4 which has caused high percentages (≥ 30%) of invasive pneumococcal disease in certain adult populations in the western United States. CDC and ACIP monitoring of the public health impact of the pneumococcal conjugate vaccines will guide future recommendations.

Section 3.0 Key Recommendations Synthesis

- People aged 12 years and older are up to date when they have received: 1 dose of the 2024–2025 Moderna COVID-19 vaccine **OR** 1 dose of the 2024–2025 Pfizer-BioNTech COVID-19 vaccine **OR** 1 dose of the 2024–2025 Novavax vaccine unless they are receiving a COVID-19 vaccine for the very first time.
- If they have never received any COVID-19 vaccine and choose to get Novavax, 2 doses of the 2024–2025 Novavax COVID-19 vaccine are needed to be up to date.

COVID-19 Vaccination for People Who Are Not Moderately or Severely Immunocompromised:

Age 19 years or older:

- Unvaccinated: 1 dose of an updated (2023–2024 Formula) mRNA COVID-19 vaccine (i.e., Moderna, Pfizer-BioNTech) OR 2 doses of updated (2023–2024 Formula) Novavax vaccine at 0, 3-8 weeks.
- Previously vaccinated (defined as having received any Original monovalent or bivalent COVID-19 vaccine (Janssen, Moderna, Novavax, Pfizer-BioNTech) prior to the updated 2023-2024 formulation) with 1 or more doses of any COVID-19 vaccine: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine administered at least 8 weeks after the most recent COVID-19 vaccine dose.
- An 8-week interval between the first and second mRNA COVID-19 vaccine (Moderna, Pfizer-BioNTech) doses and between the first and second doses of Novavax COVID-19 Vaccine might be optimal for some people as it might reduce the mild risk of myocarditis and pericarditis associated with these COVID-19 vaccines.

COVID-19 Vaccination for People Who Are Moderately or Severely Immunocompromised:

- Unvaccinated: 3-dose series of updated (2023–2024 Formula) Moderna at 0, 4, 8 weeks **OR** 3-dose series of updated (2023–2024 Formula) Pfizer- BioNTech at 0, 3, 7 weeks **OR** 2-dose series of updated (2023–2024 Formula) Novavax at 0, 3 weeks.
- Previously vaccinated with 1 dose of any Moderna: 2-dose series of updated (2023–2024 Formula) Moderna at 0, 4 weeks (minimum interval between previous Moderna dose and dose 1: 4 weeks)
- Previously vaccinated with 2 doses of any Moderna: 1 dose of updated (2023–2024 Formula) Moderna at least 4 weeks after most recent dose.

- Previously vaccinated with 1 dose of any Pfizer- BioNTech: 2-dose series of updated (2023–2024 Formula) Pfizer-BioNTech at 0, 4 weeks (minimum interval between previous Pfizer-BioNTech dose and dose 1: 3 weeks).
- Previously vaccinated with 2 doses of any Pfizer- BioNTech: 1 dose of updated (2023–2024 Formula) Pfizer-BioNTech at least 4 weeks after most recent dose.
- Previously vaccinated with 3 or more doses of any Moderna or Pfizer-BioNTech: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine at least 8 weeks after the most recent dose.
- Previously vaccinated with 1 or more doses of Janssen or Novavax with or without dose(s) of any Original monovalent or bivalent COVID-19 vaccine: 1 dose of any updated (2023–2024 Formula) of COVID-19 vaccine at least 8 weeks after the most recent dose.
- There is no preferential recommendation for the use of one COVID-19 vaccine over another when more than one recommended age-appropriate vaccine is available.

Simultaneous Administration of COVID-19 Vaccines with other Vaccines:

- Coadministration is recommended for adults if there are no contraindications at the time of the healthcare visit.

Interchangeability of COVID-19 Vaccines:

- COVID-19 vaccine doses from the same manufacturer should be administered whenever recommended.
- In the following circumstances, an age-appropriate COVID-19 vaccine from a different manufacturer may be administered:
    - Same vaccine not available at the time of the clinic visit
    - Previous dose unknown
    - Person would otherwise not receive a recommended vaccine dose
    - Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication

m-RNA COVID-19 Vaccines:

- If mRNA vaccine doses are administered from different manufacturers because of a circumstance described above, a 3-dose schedule should be followed:
    - *People ages 6 months and older who are moderately or severely immunocompromised:*
        - The second dose is administered 4 weeks after the first dose.

- The third dose of either 2024–2025 Moderna vaccine or 2024–2025 Pfizer-BioNTech vaccine is administered as follows:
    - Ages 5 years and older: at least 4 weeks after the second dose

Novavax COVID-19 Vaccine:

- People aged 12 years and older who receive a first dose of Novavax COVID-19 Vaccine should complete the 2-dose initial vaccination series with Novavax vaccine.

Safety Considerations for COVID-19 Vaccines:

mRNA COVID-19 Vaccines:

The most frequent reported reactions, by age group can be summarized as follows:

People ages 12 years and older:

- Local: Pain at the injection site; less commonly, redness and swelling and axillary swelling/tenderness.
- Systemic: Fatigue, headache, myalgia, arthralgia, and chills; less commonly, fever and nausea/vomiting.

Overall, symptoms tended to be more frequent and severe following the second dose of vaccine and among adolescents and younger adults compared with older adults.

In all age groups, most symptoms were mild to moderate in severity, typically began 1–2 days after vaccination, and resolved after 1–3 days.

Novavax COVID-19 Vaccine:

In clinical trials of Novavax COVID-19 Vaccine, the most frequent reported vaccine reactions included:

- Local: Pain/tenderness at the injection site; less commonly, redness and swelling
- Systemic: Fatigue/malaise, headache, and myalgia; less commonly, arthralgia, nausea/vomiting, and fever.

Other Vaccinations as per the 2023 Saudi Clinical Preventive Guideline:

The following table summarizes vaccine recommendations for adults aged 18 years and older along with their timing and indication:

Timing/Indication:

1. Dose annually.
2. Dose Tdap then Td booster every 10 years.

3. Pregnant women (for each pregnancy between 27 & 36 weeks).
4. For unvaccinated individuals, premarital and post-natal women if no evidence of immunity or prior disease (1 or 2 doses depend on indication).
5. If no evidence of immunity or prior disease (2 doses 8 weeks apart).
6. 2 doses 2-6 months apart for adults aged 50 years or older.
7. 3 doses (0, 1-2, and 6 months) from the first dose catch up immunization for females aged 15-26 years.
8. 1 dose adults aged 65 years or older (1 year after PCV 13 dose) from the first dose.
9. 1 dose adults with comorbid/immunocompromised conditions and adults aged 65 years or older.
10. 3 doses (0, 1 month, and 6 months) if no previous immunization or no evidence of immunity.
11. 1 dose depending on indication, then booster every 5 years if risk remains.

Recommendations for High Risk Individuals:

Typhoid:

- Among the available typhoid vaccines, TCV is preferred at all ages in view of its improved immunological properties and expected duration of protection.
- TCV - for infants and children from 6 months of age and in adults up to 45 years.
- Typhoid vaccination is recommended in response to confirmed outbreaks of typhoid fever and may be considered in humanitarian emergency settings depending on the risk assessment in the local setting.
- Countries may consider the routine use of ViPS vaccine in individuals 2 years and older, and Ty21a vaccine for individuals more than 6 years of age.
- ViPS – single dose from 2 years of age.
- Ty21a – 3-doses to be administered orally every second day from 6 years of age.
- Revaccination is recommended every 3 years for ViPS, and every 3-7 years for Ty21a.
- The potential need for revaccination with TCV is currently unclear.
- Use of the live attenuated Ty21a vaccine during pregnancy should be avoided because of theoretical safety concerns about potential adverse effects.

Cholera:

- WC vaccines (Shanchol, Euvchol, and mORCVAX) 2 doses should be given 14 days apart to individuals ≥ 1 year of age.
- For WC-rBS vaccine (Dukoral), 2 doses should be given to adults, with an interval of 1-6 weeks between doses.
- Revaccination is recommended where there is continued risk of V. cholerae infection.
- For WC vaccines revaccination is recommended after 3 years.
- For WC-rBS vaccine: For those aged ≥ 6 years of age, if less than 2 years have passed, 1 dose for revaccination. If more than 2 years have passed, the primary series of 2 doses should be repeated.
- In cholera-endemic countries, vaccination of the entire population (throughout a country regardless of risk) is usually not warranted.
- During humanitarian emergencies with a risk of cholera, but without a current cholera outbreak, vaccination with OCV should be considered as an additional preparedness measure for outbreak prevention, depending on the local infrastructure (capacity to organize a vaccination campaign).
- Pregnant and lactating women and HIV infected individuals should be included in OCV campaigns since there is a high potential benefit and minimal risks.

Hepatitis A:

- WHO recommends that vaccination against hepatitis A virus be introduced into national immunization schedules for individuals aged ≥12 months, if indicated on the basis of:
    - i) an increasing trend over time of acute hepatitis A disease, including severe disease, among older children, adolescents or adults;
    - ii) changes in the endemicity from high to intermediate;
    - iii) considerations of cost– effectiveness.
- In highly endemic countries, most individuals are asymptomatically infected with HAV in childhood, which prevents clinical hepatitis A in adolescence and adulthood.

  In these countries, large-scale hepatitis A vaccination programs are not routinely recommended, because they carry a risk of a paradoxical increase in disease incidence in unvaccinated people.

Rabies:

- There are two main immunization strategies for the prevention of human rabies:
    - PEP which includes extensive and thorough wound washing at the RABV-exposure site, together with RIG administration if indicated, and the administration of a course of several doses of rabies vaccine.
    - PrEP which is the administration of several doses of rabies vaccine before exposure to RABV.

      PrEP is recommended for individuals at high risk of RABV exposure. These include sub-populations in highly endemic settings with limited access to timely and adequate PEP, individuals at occupational risk, and travelers who may be at risk of exposure.
- For both PEP and PrEP, vaccines can be administered by either the ID or IM route:
    - One ID dose is 0.1 mL of vaccine; one IM dose is 0.5 mL or 1.0 mL depending on the product.
- The following table details the different categories of Rabies[32]:

Table 37. Rabies Categories

Category	Characteristics
Category I	Touching or feeding animals, animal licks on intact skin (no exposure)
Category II	Nibbling of uncovered skin, minor scratches or abrasions without bleeding (exposure)
Category III	Single or multiple transdermal bites or scratches, contamination of mucous membrane or broken skin with saliva from animal licks, exposures due to direct contact with bats (severe exposure).

- For category I exposures, no PEP is required.
- For category II, immediate vaccination is recommended.
- For category III, immediate vaccination is recommended, and administration of RIG, if indicated.
- PrEP schedule: 2-site ID vaccine administered on days 0 and 7.
- If IM administration is used, WHO recommends a 1-site IM vaccine administration on days 0 and 7.
- If any doses are delayed, vaccination should be resumed, not restarted.

- A change in the route of administration or in vaccine product during a PEP or PrEP course is acceptable if such a change is unavoidable.

Dengue:

- CYD-TDV is recommended as a 3-dose series given 6 months apart.
- Should a vaccine dose be delayed for any reason, it is not necessary to restart the course and the next dose in the series should be administered as soon as possible.
- CYD-TDV is not recommended in pregnant and lactating women because insufficient data are available on its use in pregnancy.
- Due to lack of data, CYD-TDV is contraindicated in immunocompromised individuals.

Special Populations:

People With Cancer:

- People with severe neutropenia:
    - People with severe neutropenia (absolute neutrophil count < 0.5×10^9 per L) should not receive any vaccines, to avoid an acute febrile episode.
- People receiving immune-oncology therapy:

    People who are receiving cancer immuno-oncology therapies (checkpoint inhibitors) may have a higher risk of adverse events following immunization with influenza vaccine; Checkpoint inhibitors include: CTLA-4 inhibitors (such as ipilimumab) and PD-1 and PD-L1 inhibitors (such as nivolumab or pembrolizumab)

    - Live vaccines are not recommended for these patients.
    - Caution is advised with inactivated vaccines, particularly the influenza vaccine.
- Live vaccines for people with cancer:
    - Live vaccines are contraindicated in cancer patients who are receiving immunosuppressive therapy and/or who have poorly controlled malignant disease.
    - Seronegative people, who are at risk of these diseases, are recommended to receive these vaccines at least 3 months after they finish chemotherapy, provided that the underlying malignancy is in remission and they are not severely immunocompromised.

- Inactivated vaccines for people with cancer:
    - People receiving chemotherapy may receive inactivated vaccines (such as pneumococcal conjugate vaccines [13vPCV, 15vPCV or 20vPCV] or hepatitis B) according to a routine or catch-up vaccination schedule. The immune response may be suboptimal, but it is safe for the person to receive these vaccines.
- HPV vaccine:
    - If the person needs HPV vaccine, 9vHPV (9-valent HPV) vaccine is recommended in a 3-dose schedule (0, 2, 6 months). This is regardless of the person's age at the start of vaccination.
- Influenza vaccine:
    - All cancer patients aged ≥6 months are recommended to receive influenza vaccine each year.
    - Cancer patients who have had a hematopoietic stem cell transplant or solid organ transplant and are receiving influenza vaccine for the 1st time after transplant are recommended to receive 2 vaccine doses at least 4 weeks apart (irrespective of age), and 1 dose each year after that.
- Pneumococcal vaccine:
    - People with underlying hematological and other generalized malignancies are recommended to receive pneumococcal vaccine.
    - Children or adults who are newly diagnosed with cancer are recommended to receive 1 dose of a pneumococcal conjugate vaccine (13vPCV or 15vPCV or 20vPCV [if ≥18 years of age]) and 2 doses of 23vPPV (23-valent pneumococcal polysaccharide vaccine).
- Zoster vaccine:
    - All cancer patients who are immunocompromised and aged ≥18 years are recommended to receive 2 doses of recombinant zoster vaccine (Shingrix) 1-2 months apart.
- COVID-19 vaccine:
    - Cancer patients who are severely immunocompromised are recommended to receive a 3rd dose of COVID-19 vaccine.
    - Recommendations for additional booster doses are based on a patient's degree of immunocompromise, age and presence of other risk factors.
- Respiratory Syncytial Virus Vaccine:

- Cancer patients aged ≥60 years are recommended to receive a single dose of an RSV vaccine.

- People who have completed cancer therapy:
  - People who have finished cancer therapy and who completed a primary vaccination schedule before diagnosis can receive most of the following vaccines without having their antibody titers checked beforehand.
  - If the person is well and in remission for 6 months after therapy, they are recommended to receive the following booster doses after they have completed their primary vaccination schedule:
    - DTPa (diphtheria-tetanus-acellular pertussis)–containing and IPV (inactivated poliovirus)–containing vaccines: Single dose of either dT or reduced antigen content dTpa if ≥10 years of age, and a single dose of IPV.
    - MMR-containing vaccine: Single dose, followed by antibody testing for immunity to measles and rubella at 6–8 weeks after vaccination. People who have not seroconverted are recommended to receive an extra dose.
    - Hepatitis B vaccine: Single dose.
    - Pneumococcal vaccines: If the full course was not received previously a single dose of a pneumococcal conjugate vaccine (13vPCV or 15vPCV or 20vPCV [if ≥18 years of age]) and 2 doses of 23vPPV after the conjugate vaccine.
    - Hib (Haemophilus influenzae type b) vaccine: Single dose if ≥ 5 years of age with asplenia.
    - Meningococcal vaccine: Single dose of MenACWY. Revaccination with MenACWY is recommended every 5 years for people with asplenia. Single dose of MenB.
    - 9vHPV vaccine: If no previous doses received, a single dose is recommended if commencing vaccination before the 26th birthday and no longer immunocompromised. A 3-dose schedule (0, 2, 6 months) is recommended if commencing vaccination from 26 years of age or if still immunocompromised.
    - Varicella vaccine: People who are seronegative for varicella-zoster virus should receive a 2-dose schedule of varicella vaccine, at least 6 months after chemotherapy has finished.

- Respiratory Syncytial Virus Vaccine: Single dose for people aged ≥60 years.

People with HIV:

- People with HIV should have vaccination schedules based on their:
  - Age
  - CD4+ count (which indicates how immunocompromised they are)
  - Risk of infection
  - Concurrent medical conditions or medications (which may be immunocompromising)
- Live attenuated vaccine considerations for people with HIV:

  BCG Vaccine

  Children or adults with HIV should not receive BCG vaccine, because of the risk of disseminated BCG infection.

  Live Cholera Vaccine

  People with HIV should not receive oral live attenuated cholera vaccine. Use the inactivated oral cholera vaccine instead.

  Japanese Encephalitis Vaccine

  People with HIV who need Japanese encephalitis vaccine should not receive the live attenuated recombinant vaccine (Imojev).

  They should receive the inactivated vaccine (JEspect) instead.

  MMR Vaccine

  Asymptomatic adults with HIV should receive 1 or 2 doses of MMR vaccine if they have a $CD4^+$ count ≥ 200 per µL and are seronegative for any of the vaccine components.

  The number of doses depends on the number of previous doses and whether they seroconvert.

  MMR vaccine does not have a significant effect on the $CD4^+$ count or viral load of adults with HIV.

  People with HIV are not recommended to receive the combination MMRV vaccine.

  Mpox Vaccine

People living with HIV can receive replication-deficient live attenuated mpox vaccine, MVA-BN (JYNNEOS), although the immune response may be reduced.

Typhoid Vaccine

People with HIV should not receive oral live attenuated typhoid vaccine. They should be given the inactivated parenteral Vi polysaccharide typhoid vaccine instead.

Varicella Vaccine

Asymptomatic adults and children ≥12 months old with HIV may receive the varicella vaccine.

Adults with HIV who are varicella seronegative and have a $CD4^+$ count of ≥200 per μL are recommended to receive 2 doses of monovalent varicella vaccine at least 3 months apart.

People with HIV are not recommended to receive the combination MMRV vaccine.

Yellow Fever Vaccine

People with HIV who are not immunocompromised ($CD4^+$ count of >200 per μL) can receive yellow fever vaccine if they are at risk of infection. People with HIV should only receive yellow fever vaccine if potential exposure to yellow fever virus is unavoidable.

Live Zoster Vaccine (Zostavax)

Adults with symptomatic HIV infection are not recommended to receive Zostavax.

People aged ≥ 50 years with asymptomatic HIV infection can receive Zostavax, if recombinant zoster vaccine (Shingrix) is not accessible, and if they; are on antiretroviral therapy, have a very low or undetectable viral load, and have a $CD4^+$ count of ≥ 350 per μL.

If there is a strong indication to vaccinate, some experts suggest that adults with a $CD4^+$ count of >200 per μL can safely receive Zostavax.

Zostavax is only registered for use in adults ≥50 years of age.

- **Inactivated Vaccines for People with HIV:**

  Meningococcal Vaccines

  People with HIV are recommended to receive MenACWY and MenB vaccines.

People with HIV may have a diminished immune response after a single dose of MenACWY. However, this improves for some serogroups after a 2nd dose.

There are no clinical data on the use of MenB vaccine in people with HIV. Vaccination is recommended based on the expected benefit in these people.

HPV Vaccine

Adults with HIV can receive the 9vHPV vaccine.

HPV vaccines are safe and immunogenic in people with HIV.

People with HIV are recommended to receive a 3-dose course of 9vHPV vaccine at 0, 2 and 6 months regardless of their age when they started vaccination.

Males aged 27–45 years who receive HPV vaccine are unlikely to have different immunogenicity or adverse events compared with females in this age group, for whom the vaccine is currently registered. However, these men may have less benefit if they have already been infected with HPV.

DTPa/dTpa, Hib and IPV Vaccines

People with HIV can receive DTPa or dTpa, Hib and IPV vaccines according to routine recommendations.

Hepatitis A Vaccine

Hepatitis A vaccine is only recommended for use in non-immune people with HIV if they have independent risk factors for acquiring hepatitis A.

Hepatitis B Vaccine

People with HIV can safely receive hepatitis B vaccine.

Because of immune suppression, they may have a diminished immunological response.

Limited studies in HIV1-positive adults show an improved and accelerated serological response to a vaccination schedule that comprises 4 double doses. This means 2 injections of the standard adult dose (using Engerix-B) on each occasion, at 0, 1, 2 and 6 months.

Influenza Vaccine

All adults and children (≥ 6 months of age) with HIV are recommended to receive influenza vaccine every year.

Pneumococcal Vaccine

Children aged > 12 months and adults who are newly diagnosed with HIV are recommended to receive a single dose of a pneumococcal conjugate vaccine (PCV) (13vPCV, 15vPCV or 20vPCV [if ≥18 years of age]), followed by 2 doses of 23vPPV. If they have previously received doses of 23vPPV, they are recommended to receive the dose of the pneumococcal conjugate vaccine 12 months after their last 23vPPV dose. If they have already received at least 2 doses of 23vPPV, no further 23vPPV doses are recommended.

Q fever Vaccine

There are no data on Q fever vaccine in people with HIV.

Q fever vaccine is contraindicated in people who are immunocompromised.

Typhoid, Japanese Encephalitis and Rabies Vaccines

People with HIV can safely receive the following vaccines if they are travelling or living in an at-risk area:

- Parenteral Vi Polysaccharide Typhoid Vaccine
- Inactivated oral cholera vaccine (Dukoral)
- Inactivated Japanese Encephalitis Vaccine (Jespect)
- Rabies Vaccine

Recombinant Zoster Vaccine (Shingrix)

People aged ≥18 with HIV can safely receive recombinant zoster vaccine (Shingrix), and this is the preferred zoster vaccine for this population.

COVID-19 Vaccine

People with HIV who have CD4 counts < 250/μL, or those with a higher CD4 count unable to be established on effective antiretroviral therapy (ART) are recommended to receive a 3rd primary dose of COVID-19 vaccine.

A 3rd primary dose is not required for people receiving ART who have CD4 counts ≥ 250/μL.

Respiratory Syncytial Virus Vaccine

People aged ≥60 years with HIV are recommended a single dose of RSV vaccine.

Section 4.0 Conclusion

This report serves as **an annex to the previous CHI Adult Immunization report** and aims to provide recommendations to aid in Adult Immunization. It is important to note that these recommendations should be utilized to support clinical decision-making and not replace it for immunization processes. Health professionals are expected to consider this guidance alongside the specific needs, preferences, and values of their patients when exercising their judgment.

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Section 6.0 Appendices

Appendix A. Prescribing Edits Definition

Some covered drugs may have additional requirements, rules or limits on coverage. These requirements and limits may include:

Prescribing edits Tools	Description
AGE (Age):	Coverage may depend on patient age
CU (Concurrent Use):	Coverage may depend upon concurrent use of another drug
G (Gender):	Coverage may depend on patient gender
MD (Physician Specialty):	Coverage may depend on prescribing physician's specialty or board certification
PA (Prior Authorization):	Requires specific physician request process
QL (Quantity Limits):	Coverage may be limited to specific quantities per prescription and/or time period
ST (Step Therapy):	Coverage may depend on previous use of another drug
EU (Emergency Use only):	This drug status on Formulary is only for emergency use
PE (Protocol Edit):	Use of drug is dependent on protocol combination, doses and sequence of therapy

Appendix B. Level of Evidence Description

Grade of research	
A	Strongly recommend; good evidence
B	Recommend; at least fair evidence
C	No recommendation for or against; balance of benefits and harms too close to justify a recommendation
D	Recommend against; fair evidence is ineffective, or harm outweighs the benefit
E	Evidence is insufficient to recommend for or against routinely; evidence is lacking or of poor quality; benefits and harms cannot be determined
Level of evidence	
Level I	Meta-analysis of multiple studies
Level II	Experimental studies
Level III	Well-designed, quasi-experimental studies
Level IV	Well-designed, non-experimental studies
Level V	Case reports and clinical examples

Appendix C. PubMed Search Methodology Terms

The following PubMed Search Methodology was opted:

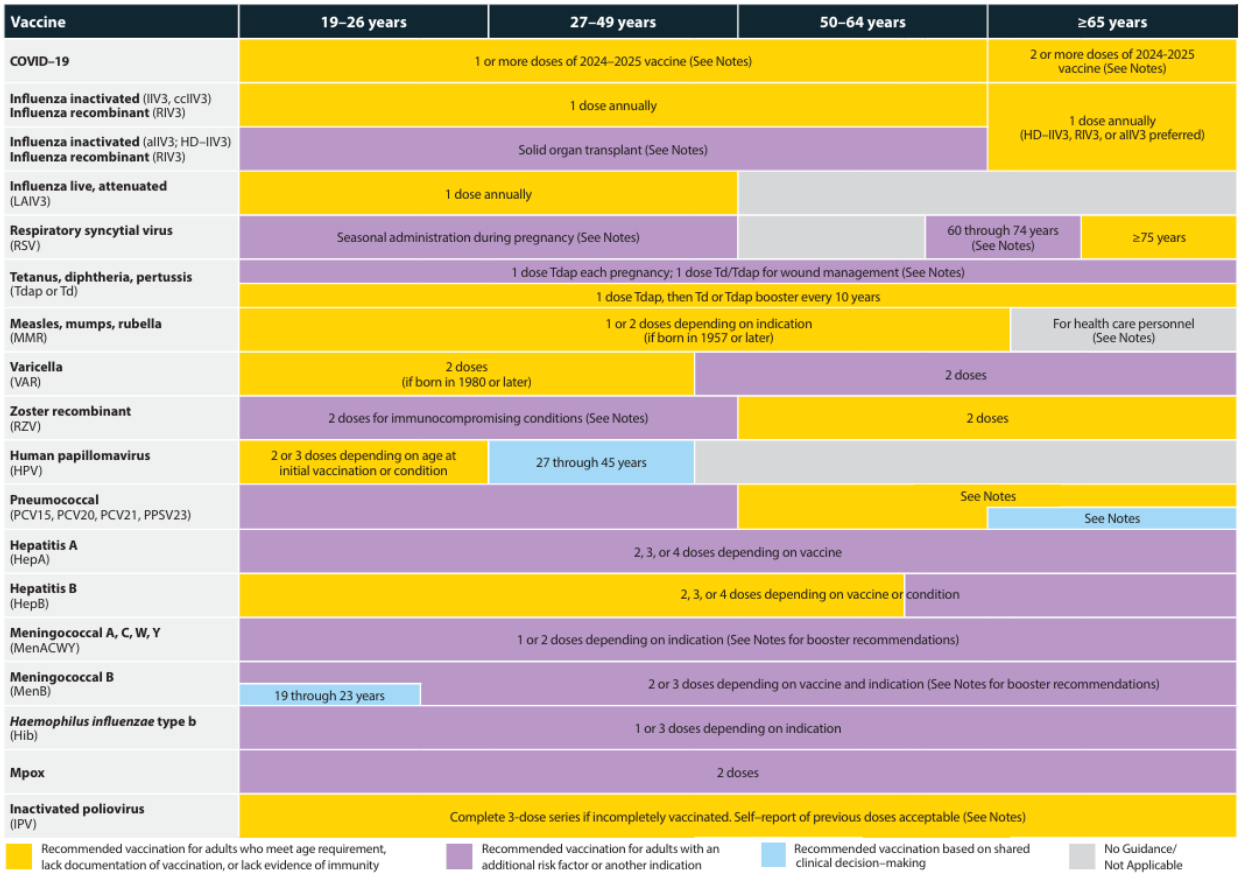
Query	Sort By	Filters	Search Details	Results
((((((((((((((((Immunization[MeSH Terms]) OR (Immunizations[Title/Abstract])) OR (Immunologic Sensitization[Title/Abstract])) OR (Sensitization, Immunologic[Title/Abstract])) OR (Stimulation, Immunologic[Title/Abstract])) OR (Immunologic Stimulation[Title/Abstract])) OR (Immunostimulation[Title/Abstract])) OR (Immunological Stimulation[Title/Abstract])) OR (Immunological Stimulations[Title/Abstract])) OR (Stimulation, Immunological[Title/Abstract])) OR (Stimulations, Immunological[Title/Abstract])) OR (Sensitization, Immunological[Title/Abstract])) OR (Immunological Sensitization[Title/Abstract])) OR (Immunological Sensitizations[Title/Abstract])) OR (Sensitizations, Immunological[Title/Abstract])) OR (Variolation[Title/Abstract])) OR (Variolations[Title/Abstract])) AND ((Adult[MeSH Terms]) OR (Adults[Title/Abstract]))			("vaccination"[MeSH Terms] OR "immunization"[MeSH Terms] OR "Immunizations"[Title/Abstract] OR "immunologic sensitization"[Title/Abstract] OR "sensitization immunologic"[Title/Abstract] OR "stimulation immunologic"[Title/Abstract] OR "immunologic stimulation"[Title/Abstract] OR "Immunostimulation"[Title/Abstract] OR "immunological stimulation"[Title/Abstract] OR "immunological stimulations"[Title/Abstract] OR (("stimulate"[All Fields] OR "stimulated"[All Fields] OR "stimulates"[All Fields] OR "stimulating"[All Fields] OR "Stimulation"[All Fields] OR "Stimulations"[All Fields] OR "stimulative"[All Fields] OR "stimulator"[All Fields] OR "stimulator s"[All Fields] OR "stimulators"[All Fields]) AND "Immunological"[Title/Abstract]) OR (("stimulate"[All Fields] OR "stimulated"[All Fields] OR "stimulates"[All Fields] OR "stimulating"[All Fields] OR "Stimulation"[All Fields] OR "Stimulations"[All Fields] OR "stimulative"[All Fields] OR "stimulator"[All	46,657

			Fields] OR "stimulator s"[All Fields] OR "stimulators"[All Fields]) AND "Immunological"[Title/Abstract]) OR "sensitization immunological"[Title/Abstract] OR "immunological sensitization"[Title/Abstract] OR (("allergy and immunology"[MeSH Terms] OR ("allergy"[All Fields] AND "immunology"[All Fields]) OR "allergy and immunology"[All Fields] OR "Immunologic"[All Fields] OR "Immunological"[All Fields] OR "immunologically"[All Fields] OR "immunologicals"[All Fields]) AND "Sensitizations"[Title/Abstract]) OR (("sensitisation"[All Fields] OR "sensitisations"[All Fields] OR "sensitise"[All Fields] OR "sensitised"[All Fields] OR "sensitiser"[All Fields] OR "sensitisers"[All Fields] OR "sensitises"[All Fields] OR "sensitising"[All Fields] OR "Sensitization"[All Fields] OR "Sensitizations"[All Fields] OR "sensitize"[All Fields] OR "sensitized"[All Fields] OR "sensitizer"[All Fields] OR "sensitizers"[All Fields] OR "sensitizes"[All Fields] OR "sensitizing"[All Fields]) AND "Immunological"[Title/Abstract]) OR "Variolation"[Title/Abstract]	

			OR "Variolations"[Title/Abstract]) AND ("adult"[MeSH Terms] OR "Adults"[Title/Abstract])	

Appendix D. Immunization Schedule Scheme

The following Vaccination Scheme was opted from the 2025 CDC Immunization Schedule for Adults[14]:



Appendix E. Modification Log Table

Section	Modification done
Executive summary	Added title of new/updated guidelines Added new SFDA registered drugs (Gardasil® 9 and Abrysvo®) Moved Arexvy® and Prevnar 20® from non-SFDA drugs to SFDA drugs Listed new non-SFDA registered drugs (Capvaxive® and Mresvia®)
Section 1.1.1 and Section 1.1.2	Updated recommendations
Section 1.2.1 - Section 1.2.4	Updated recommendations
Section 2.1	Added an information table for four newly SFDA registered drugs (Prevnar 20®, Arexvy®, Abrysvo® and Gardasil® 9) Added HTA recommendations and conclusions for each of the newly SFDA registered drugs
Section 2.4	Moved Arexvy® and Prevnar 20® from non-SFDA drugs to SFDA drugs Added new non-SFDA registered drugs (Capvaxive® and Mresvia®)
Section 3.0	Updated the Key Recommendations Synthesis table based on new findings
Section 5.0	Updated References
Appendix C	Updated PubMed Search Methodology Terms
Appendix D	Updated the Adult Immunization Schedule Components