ADULT IMMUNIZATION

CHI Formulary Development Project

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Council of Health Insurance

INDICATION UPDATE

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ADDENDUM to the CHI Original Adult Immunization Clinical Guidance- Issued February 2020

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Related Documents

Related SOPs

- IDF-FR-P-02-01-IndicationsReview&IDFUpdates
- IDF-FR-P-05-01-UpdatedIndicationReview&IDFUpdates

Related WI:

- IDF-FR-WI-01-01SearchMethodologyGuideForNewIndications

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Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
aIIV4	Quadrivalent Adjuvanted Inactivated Influenza Vaccine
ALT	Alanine Transaminase
AST	Aspartate Transaminase
bDMARDs	biological DMARDs
CADTH	Canadian Agency for Drugs and Technologies in Health
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
DMARDs	Disease-Modifying Antirheumatic Drugs
EZV	Ebola Zaire vaccine
GBS	Guillain-Barré syndrome
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
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
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 IHME 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 DALYs 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 IDF (CHI Drug Formulary) while addressing **the most updated best available clinical and economic evidence related to vaccines.**

Main triggers for the update are summarized, being **the issuance of updated versions of previously reviewed guidelines** as the 2023 Center for Disease Control and Prevention (CDC) Immunization Schedule for Adults and the 2023 UK Immunization Schedule. **New guidelines are added to the report** such as the 2023 Saudi Preventive Guideline, the 2023 WHO Routine Immunization Schedule, the 2023 Australian National Immunization Program Schedule and the 2023 Canada's Improving Adult Immunization. Other triggers include **newly approved SFDA registered vaccines** as the Spikevax® mRNA COVID-19 vaccine and Vaxneuvance® Pneumococcal 15-Valent Conjugate Vaccine, **newly approved non-SFDA registered vaccines** as Comirnaty® mRNA COVID-19 Vaccine, Arexvy® Respiratory Syncytial Virus Vaccine, PreHevbrio® Hepatitis B Vaccine, MenQuadfi® Meningococcal Vaccine, Penbraya® Meningococcal Vaccine, and Prevnar 20® Pneumococcal 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
Spikevax®, COVID-19 Vaccine (mRNA-1273)	COVID-19 Prevention	Strong Recommendation[7]	Positive Recommendation from HAS[8].
Vaxneuvance® (Pneumococcal 15-Valent Conjugate Vaccine)	Prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5,	Strong Recommendation[9]	No HTA recommendations have been issued for Vaxneuvance®.

	6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F		

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]
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.	Strong Recommendation[10]
PreHevbrio® (Hepatitis B Vaccine, Recombinant)	Hepatitis B Virus Prevention	Strong Recommendation[11]
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[12]
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[13]
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,	Strong Recommendation[14]

	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.	

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 **[2023]**
UK Immunization Schedule **[2020]**	UK Immunization Schedule **[2023]**

1.1.1 Center for Disease Control and Prevention (CDC) Immunization Schedule for Adults [2023]

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 2023 updated vaccination schedule along with recommendations for the optimization of Adult Immunization; the recommendations are detailed below[15]:

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

Ages 12 Years and 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.
- Previously received 1 or more Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- Previously received 1 or more doses of Original monovalent Novavax vaccine, alone or in combination with any Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- Previously received 1 or more doses of Janssen vaccine, alone or in combination with any Original monovalent or bivalent mRNA vaccine or Original monovalent Novavax doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- 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.
- The extended interval consideration applies only to people who are not moderately or severely immunocompromised and aged 12 years–64 years and receiving a 2-dose Novavax series.

- 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).
- An elevated risk for myocarditis and pericarditis has been observed among mRNA COVID-19 vaccine recipients, particularly in males ages 12–39 years.
- 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

COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine*	Updated (2023–2024 Formula) vaccine	Number of updated (2023–2024 Formula) doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors§	Interval between doses
Unvaccinated	Moderna	1	0.5 mL/50 ug	Dark blue cap; blue label	—
	OR				
	Novavax	2	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label	Dose 1 and Dose 2: 3–8 weeks
	OR				
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	—
1 or more doses any mRNA; 1 or more doses Novavax or Janssen, including in	Moderna	1	0.5 mL/50 ug	Dark blue cap; blue label	At least 8 weeks after last dose

combination with any Original monovalent or bivalent COVID-19 vaccine doses					
	OR				
	Novavax	1	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label	At least 8 weeks after last dose
	OR				
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	At least 8 weeks after last dose

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

Ages 12 Years and Older:

- Unvaccinated: 3 homologous (i.e., from the same manufacturer) updated (2023–2024 Formula) mRNA vaccine doses (i.e., Moderna, Pfizer-BioNTech) **OR** 2 updated (2023–2024 Formula) Novavax vaccine doses.
- Previously received 1 or 2 Original monovalent or bivalent mRNA vaccine doses: Complete the 3-dose series with 2 or 1 homologous updated (2023–2024 Formula) mRNA vaccine doses, respectively.
- Previously received a combined total of 3 or more Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- Previously received 1 or more Original monovalent Novavax vaccine doses, alone or in combination with any Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- Previously received 1 or more doses of Janssen vaccine, alone or in combination with any Original monovalent or bivalent mRNA vaccine or Original monovalent Novavax doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).

- Additional doses: May receive 1 or more additional doses of an updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) following the last recommended updated (2023–2024 Formula) COVID-19 vaccine dose.
- The following table describes the recommended COVID-19 Vaccination Schedule for patients who are moderately or severely immunocompromised:

Table 5. Recommended COVID-19 Vaccination Schedule for Patients Who Are Moderately or Severely Immunocompromised

COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine†	Updated (2023–2024 Formula) vaccine	Number of updated (2023–2024 Formula) doses indicated‡	Dosage (mL/ug)	Vaccine vial cap and label colors§	Interval between doses
Unvaccinated	Moderna	3	0.5 mL/50 ug	Dark blue cap; blue label	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
	OR				
	Novavax	2	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label	Dose 1 and Dose 2: 3 weeks
	OR				
	Pfizer-BioNTech	3	0.3 mL/30 ug	Gray cap; gray label	Dose 1 and Dose 2: 3 weeks Dose 2 and Dose 3: At least 4 weeks

1 dose any Moderna	Moderna	2	0.5 mL/50 ug	Dark blue cap; blue label	Dose 1: 4 weeks after last dose Dose 1 and Dose 2: At least 4 weeks
2 doses any Moderna	Moderna	1	0.5 mL/50 ug	Dark blue cap; blue label	At least 4 weeks after last dose
1 dose any Pfizer-BioNTech	Pfizer-BioNTech	2	0.3 mL/30 ug	Gray cap; gray label	Dose 1: 3 weeks after last dose Dose 1 and Dose 2: At least 4 weeks
2 doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	At least 4 weeks after last dose
3 or more doses any mRNA vaccine	Moderna	1	0.5 mL/50 ug	Dark blue cap; blue label	At least 8 weeks after last dose
	OR				
	Novavax	1	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label	At least 8 weeks after last dose
	OR				
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	At least 8 weeks after last dose
1 or more doses Novavax or Janssen, including in	Moderna	1	0.5 mL/50 ug	Dark blue cap; blue label	At least 8 weeks after last dose

combination with any Original monovalent or bivalent COVID-19 vaccine doses	OR				
	Novavax	1	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label	At least 8 weeks after last dose
	OR				
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	At least 8 weeks after last dose

- 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

4-Day Grace Period:

- Doses administered up to 4 days before the minimum interval, known as the 4-day grace period, are considered valid.
- Known as the "grace period", vaccine doses administered ≤4 days before the minimum interval or age are considered valid; however, local or state mandates might supersede this 4-day guideline.

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:

Interchangeability of mRNA COVID-19 Vaccines:

- People aged 5 years and older who are moderately or severely immunocompromised should receive a 3-dose initial mRNA vaccination series **using vaccines from the same manufacturer**.
- For people who receive 1 Moderna and 1 Pfizer-BioNTech vaccine dose, the initial vaccination series is completed as follows:
    - People ages 6 months and older who are moderately or severely immunocompromised should follow the recommended 3-dose schedule. A third dose of either updated (2023–2024 Formula) Moderna vaccine or updated (2023–2024 Formula) Pfizer-BioNTech vaccine should be administered as follows:
        - Aged 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.

Precautions/Contraindications to COVID-19 Vaccination:

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

Table 6. 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:

Adults:

- Local: Pain at the injection site; less commonly, redness and swelling
- Systemic: Fatigue, headache, and myalgia

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

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

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.

Among people ages 18 years and older who received the Novavax booster dose, symptoms were more frequently reported after the booster dose than dose 2 of the primary series.

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

- **For People Exposed to SARS-CoV-2:**
    - COVID-19 vaccines **are not recommended for post-exposure prophylaxis**.
    - People with a known or potential SARS-CoV-2 exposure may receive the vaccine if they do not have symptoms consistent with COVID-19.
- **For People with Prior or Current 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 prolonged post-COVID-19 symptoms.
    - People with known current SARS-CoV-2 infection should defer any COVID-19 vaccination at least until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.
    - 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).
    - Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection **is not recommended for the purpose of vaccine decision-making.**

Pregnancy, Lactation and Fertility Considerations:

- 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: Heplisav-B and PreHevbrio are 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.
    - 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

- **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)

Human Papilloma Virus Vaccination:

- ACIP recommends vaccination for everyone through age 26 years if not adequately vaccinated when younger.
- HPV vaccination is given as a series of either two or three doses, depending on age at initial vaccination.
- Vaccination is not recommended for everyone older than age 26 years. Some adults ages 27 through 45 years might decide to get the HPV vaccine based on discussion with their clinician, if they did not get adequately vaccinated when they were younger. HPV vaccination of people in this age range provides less benefit, for several reasons, including that more people in this age range have already been exposed to HPV.
- For adults ages 27 through 45 years, clinicians can consider discussing HPV vaccination with people who are most likely to benefit. HPV vaccination does not need to be discussed with most adults over age 26 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[16].

- 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[17].
- Three doses of HPV vaccine are recommended for teens and young adults who start the series at ages 15 through 26 years, and for immunocompromised persons.
- The recommended three-dose schedule is 0, 1–2 and 6 months.
- Three doses are recommended for immunocompromised persons (including those with HIV infection) aged 9 through 26 years.
- A severe allergic reaction (e.g., anaphylaxis) to a vaccine component or following a prior dose of HPV vaccine is a contraindication to receipt of HPV vaccine.
- 9-valent HPV vaccine is produced in Saccharomyces cerevisiae (baker's yeast) and is contraindicated for persons with a history of immediate hypersensitivity to yeast.
- A moderate or severe acute illness is a precaution to vaccination, and vaccination should be deferred until symptoms of the acute illness improve.
- A minor acute illness (e.g., diarrhea or mild upper respiratory tract infection, with or without fever) is not a reason to defer vaccination.
- HPV vaccine is not recommended for use during pregnancy.
- **Interrupted schedules:**
    - If vaccination schedule is interrupted, the series does not need to be restarted
- **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.

- **Age 65 years or older:** Any one of quadrivalent high-dose inactivated influenza vaccine (HD-IIV4), quadrivalent recombinant influenza vaccine (RIV4), or quadrivalent adjuvanted inactivated influenza vaccine (aIIV4) 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 LAIV4.
        - If LAIV4 is given, they should avoid contact with/caring for such immunosuppressed persons for 7 days after vaccination.
    - History of Guillain-Barré syndrome within 6 weeks after previous dose of influenza vaccine:
        - Generally, should not be vaccinated unless vaccination benefits outweigh risks for those at higher risk for severe complications from influenza.

Measles, Mumps, and Rubella Vaccination:

- **Special Situations:**
    - 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.

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-D (Menactra, 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 (Menactra, 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 (Menactra, 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:
        - Based on shared clinical decision-making, 2-dose series MenB-4C (Bexsero) at least 1 month apart or 2-dose series MenB-FHbp (Trumenba) at 0, 6 months (if dose 2 was administered less than 6 months after dose 1, administer dose 3 at least 4 months after dose 2); MenB-4C and MenB-FHbp are not interchangeable (The same product should be used for all doses in series)
- **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:
        - 2-dose primary series MenB-4C (Bexsero) at least 1 month apart or 3-dose primary series MenB-FHbp (Trumenba) 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 fourth dose should be administered at least 4 months after dose 3); MenB-4C and MenB-FHbp are not interchangeable (use same product for all doses in series); 1 dose MenB booster 1 year after primary series and revaccinate 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.

Pneumococcal Vaccination:

- **Age 65 years or older who have:**
    - **Not previously received a dose of PCV13, PCV15, or PCV20 or whose previous vaccination history is unknown:**
        - 1 dose PCV15 **OR** 1 dose PCV20.
        - 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 to minimize the risk of invasive pneumococcal disease caused by serotypes unique to PPSV23 in these vulnerable groups.
    - **Previously received only PCV7:**
        - follow the recommendation above.
    - **Previously received only PCV13:**
        - 1 dose PCV20 at least 1 year after the PCV13 dose OR complete the recommended PPSV23 series.
    - **Previously received only PPSV23:**
        - 1 dose PCV15 **OR** 1 dose PCV20 at least 1 year after the PPSV23 dose. If PCV15 is used, it need not be followed by another dose of PPSV23.
    - **Previously received both PCV13 and PPSV23 but NO PPSV23 was received at age 65 years or older:**
        - 1 dose PCV20 at least 5 years after their last pneumococcal vaccine dose **OR** complete the recommended PPSV23 series.
    - **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 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 19–64 years with certain underlying medical conditions or other risk factors who have:
        - **Not previously received a PCV13, PCV15, or PCV20 or whose previous vaccination history is unknown:**
            - 1 dose PCV15 **OR** 1 dose PCV20. 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 at least 1 year after the PCV13 dose **OR** complete the recommended PPSV23 series.
        - **Previously received only PPSV23:**
            - 1 dose PCV15 **OR** 1 dose PCV20 at least 1 year after the PPSV23 dose. If PCV15 is used, it need not be followed by another dose of PPSV23.
        - **Previously received both PCV13 and PPSV23 but have not completed the recommended series:**
            - 1 dose PCV20 at least 5 years after their last pneumococcal vaccine dose **OR** complete the recommended PPSV23 series.
- 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: Except in rare circumstances (e.g. no available personal protective equipment), healthcare personnel who do not have any of the sexual risk factors described above should not receive the vaccine.

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 **Special Situations:**
    - **Adults at increased risk of exposure to poliovirus with:**
        - No evidence of a complete polio vaccination series (i.e., at least 3 doses):
            - Administer remaining doses (1, 2, or 3 doses) to complete a 3-dose series.
        - Evidence of completed polio vaccination series (i.e., at least 3 doses):
            - May administer one lifetime IPV booster.

Tetanus, diphtheria, and pertussis (Tdap) Vaccination:

- **Special Situations:**
    - **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

- **Special Situations:**
    - 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.

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.
- **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 7. ACIP 2023 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. ▪ Adults 60 years of age and older may receive a single dose of Respiratory Syncytial Virus (RSV) vaccine, using shared clinical decision-making.

COVID-19 (Moderna, Pfizer-BioNTech)	All persons ≥6 months of age should receive 2023–2024 (monovalent, XBB containing) COVID-19 vaccines as authorized under EUA or approved by BLA.
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.

Contraindications and Precautions:

The following table was adapted from the 2023 ACIP Clinical Guideline:

Table 8. Vaccines Contraindications and Precautions

Vaccine	Contraindicated or Not Recommended	Precautions
Influenza, egg-based, inactivated injectable (IIV4)	• 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 [(ccIIV4), Flucelvax® Quadrivalent]	• Severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency, or to any component of ccIIV4	• 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 ccIV4, 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 [(RIV4), Flublok® Quadrivalent]	• Severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency, or to any component of RIV4	• 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 RIV4, 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 [LAIV4, Flumist® Quadrivalent]	• 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 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	• 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)] • Moderate or severe acute illness with or without fever

	48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days.	
Haemophilus influenzae type b (Hib)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • For Hiberix, ActHib, and PedvaxHIB only: History of severe allergic reaction to dry natural latex	• 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: Heplisav-B and PreHevbrio are not recommended due to lack of safety data in pregnant persons. Use other hepatitis B vaccines if HepB is indicated	• Moderate or severe acute illness with or without fever
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-D (Menactra®); MenACWY-TT (MenQuadfi®)]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • For MenACWY-D and MenACWY-CRM only: severe allergic reaction to any diphtheria toxoid– or CRM197–containing vaccine	• Moderate or severe acute illness with or without fever

	• For MenACWY-TT only: severe allergic reaction to a tetanus toxoid-containing vaccine	
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
Pneumococcal conjugate (PCV15, PCV20)	• 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–containing vaccine or to its vaccine component	• Moderate or severe acute illness with or without fever
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
Tetanus, diphtheria, and acellular pertussis (Tdap)	• 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
Tetanus, diphtheria (Td)	• 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 [2023]

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 2023 complete routine immunization schedule updated in October of 2023; the recommendations are detailed below:

Table 9. 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

The following tables provides proposed selective immunization programs:

Table 10. 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
Pregnant Women	From 16 weeks gestation	Pertussis	dTaP/IPV (Boostrix-IPV)

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

Table 11. 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	Pneumococcal	PCV13 (up to 10 years of age)

Parkinson's or motor neuron disease, or learning disability)		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	Meningococcal groups A, B, C, W and Y	MenACWY MenB

complement inhibitor therapy)		
	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 12. List of Additional Guidelines

Additional Guidelines
KSA: Saudi Clinical Preventive Guideline [2023]
North American: WHO Routine Immunization Schedule [2023]
International: - Australian National Immunization Program Schedule [2023] - Canada's Improving Adult Immunization [2015] with a partial content update in 2023

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 13. 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	Offer or provide this service.

	is moderate certainty that the net benefit is moderate to substantial.	
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 benefits and harms cannot be determined.	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.

- 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 [2023]

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[18–20]:

Table 14. 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 containing vaccine			Coverage criteria > 80% Combination vaccine
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

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.

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.

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.
- 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.
- 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:

- 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[21]:

Table 15. 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 programme, 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 VE 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:

Table 16. 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 [2023]

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[22]:

The following table details all required adult immunizations:

Table 17. Adult Vaccination. Adapted from the Australian National Immunization Program Schedule (2023)

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

Conditions
Immunocompromising Conditions Including: • HIV Infection • Malignancy • Chronic Steroid Use • Solid Organ Transplant • Hematopoietic Stem Cell Transplant
Functional or Anatomical Asplenia, Including: • Sickle Cell Disease or Other Haemoglobinopathies • Congenital Or Acquired Asplenia (For Example, Splenectomy) Or Hyposplenia
Cardiac Disease, Including:

- Cyanotic 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

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

Chronic Renal Failure

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

Chronic Liver Disease

Down Syndrome

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 19. 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 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 20. 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, an additional (3rd) dose of 13vPCV in infancy, followed by a routine booster dose at age 12 months (as with other healthy children), then followed by 2 doses of 23vPPV. Refer to the Immunization Handbook
≥ 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

<u>Special Populations:</u>

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.
    - 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.
- 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.

Solid Organ Transplant Recipients:

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

Table 21. 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 (eg 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 polysaccharide vaccine)	Yes (2–12 months after a dose of PCV (pneumococcal conjugate vaccine [13vPCV, 15vPCV or 20vPCV]))	Yes (2–12 months after a dose of PCV (13vPCV, 15vPCV or 20vPCV)	• 2 doses at least 5 years apart.
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.
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.

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.
    - **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.
    - **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.
  - **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 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.

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 [2023]

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[23]:

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

Table 22. 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)	• Women up to and including 26 years of age - bivalent (HPV2) or quadrivalent (HPV4) or nonavalent (HPV9) vaccine • Men up to and including 26 years of age - HPV4 or HPV9 vaccine
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 polysaccharide 23-valent	65 years of age and older - 1 dose
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 23. 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: o With chronic diseases at risk for complications o At increased risk of acquiring travelers' diarrhea o Who are immunosuppressed o 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)	• Quadrivalent or nonavalent HPV vaccine may be considered for men and women 27 years of age and older at ongoing risk of exposure • Bivalent HPV vaccine may be considered for women 27 years of age and older at ongoing risk of exposure
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:

	○ Non-immune military personnel or health care workers - 2 doses, at least 4 weeks apart ○ Non-immune travelers - 1 dose ○ 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 polysaccharide 23-valent	Recommended for adults without immunosuppression: • Who are residents of long-term care facilities • Who are at increased risk of IPD due to lifestyle factors: ○ Persons with alcoholism ○ Smokers ○ Persons who are homeless ○ Should be considered for individuals who use illicit drugs

	• Who are at high risk of IPD due to an underlying medical condition:
	  ○ Asthma requiring regular medical care
	  ○ Chronic cerebral spinal fluid leak
	  ○ Chronic neurologic condition that may impair clearance of oral secretions
	  ○ Cochlear implants (including adults who are to receive implants)
	  ○ Chronic cardiac or pulmonary disease
	  ○ Diabetes mellitus
	  ○ Chronic kidney disease
	  ○ Chronic liver disease (including hepatic cirrhosis due to any cause)
	Recommended for adults with immunosuppression following immunization with pneumococcal conjugate 13-valent vaccine

Pneumococcal conjugate 13-valent	Recommended for adults with immunosuppression: • Asplenia (functional or anatomic) • Sickle cell disease or other hemoglobinopathies • Congenital immunodeficiencies involving any part of the immune system, including B-lymphocyte (humoral) immunity, T-lymphocyte (cell) mediated immunity, complement system (properdin or factor D deficiencies), or phagocytic functions • HIV infection • Immunosuppressive therapy including use of long-term corticosteroids, chemotherapy, radiation therapy, post-organ transplant therapy, and biologic and non-biologic immunosuppressive therapies for rheumatologic and other inflammatory diseases • Malignant neoplasms including leukemia and lymphoma • Solid organ or islet cell transplant (candidate or recipient) • Nephrotic syndrome • Following HSCT
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
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 specific immunization schedule for those who are not moderately to severely immunocompromised:

Table 24. COVID-19 Immunization for Patients who are not Moderately to Severely Immunocompromised

Vaccine Product (Dose)	Immunization Schedule	Authorized Age Indication	Minimum Interval	Authorized Interval	Optimal Interval
Pfizer BioNTech vaccines					
Comirnaty Omicron XBB.1.5 (30 mcg)	Authorized as one dose; NACI currently recommends 2 doses (under review)	12 years of age and over	no data	N/A	8 weeks
Comirnaty bivalent BA.4/5 (30 mcg)	2-dose schedule	12 years of age and older	no data	21 days	8 weeks
Moderna vaccines					
Spikevax XBB.1.5 (50 mcg)	Authorized as one dose; NACI currently recommends	12 years of age and over	no data	28 days	8 weeks

	2 doses (under review)				
Spikevax bivalent BA.4/5 (50 mcg)	NACI currently recommends 2 doses	12 years of age and older	no data	N/A	8 weeks
Novavax vaccine					
Nuvaxovid	2-dose schedule	12 years of age and older	21 days	21 days	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:
    - It is recommended that a complete vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are pregnant or breastfeeding.
    - Booster recommendations for individuals at increased risk of severe illness from COVID-19 apply to people who are pregnant. An individual may receive all doses for which they are eligible during the course of a pregnancy, regardless of the trimester of pregnancy.
    - An mRNA vaccine is preferred due to reassuring published data on the safety of these vaccines in pregnancy.
- For Immunocompromised patients:
    - Those who are moderately to severely immunocompromised should receive an extra dose in the primary series and then subsequent booster doses as recommended following the primary series.

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 COVID-19 Vaccinations

2.1.1.1 Spikevax, COVID-19 Vaccine (mRNA-1273) – Moderna

Table 25. Spikevax® Drug Information

SCIENTIFIC NAME **COVID-19 Vaccine (mRNA)**	
SFDA Classification	Prescription
SFDA Approval	Yes
US FDA	Yes
EMA	Yes
MHRA	Yes
PMDA	Yes
Indication (ICD-10)	U07.1
Drug Class	Vaccine
Drug Sub-class	COVID-19 Vaccine (mRNA)
ATC Code	J07BN01
Pharmacological Class (ASHP)	COVID-19 Vaccine (mRNA)
DRUG INFORMATION	
Dosage Form	Suspension, Intramuscular Suspension Prefilled Syringe, Intramuscular
Route of Administration	Intramuscular Route
Dose (Adult) [DDD]*	**Primary Series:**

	Individuals 12 years of age and older: Spikevax is administered as a course of 2 (two) 100 microgram doses (0.5 mL each). **Severely immunocompromised aged 6 years and older:** A third dose may be given at least 28 days after the second dose to individuals 12 years of age and older (0.5 mL, 100 micrograms) **Booster dose:** Individuals 12 years of age and older A booster dose of Spikevax (0.25 mL, containing 50 micrograms mRNA, which is half of the primary dose) should be given intramuscularly to individuals 12 years of age and older at least 3 months after completion of the primary series.
Maximum Daily Dose Adults*	N/A
Dose (pediatrics)	**Primary Series:** Children 6 through 11 years of age: Spikevax is administered as a course of 2 (two) 50 microgram doses (0.25 mL each, containing 50 micrograms mRNA, which is half of the primary dose for individuals 12 years and older). It is recommended to administer the second dose 28 days after the first dose **Severely immunocompromised aged 6 years and older:** A third dose may be given at least 28 days after the second dose to individuals 12 years of age and older (0.5 mL, 100 micrograms) and children 6 through 11 years (0.25 mL, 50 micrograms) who are severely immunocompromised **Booster dose:** Individuals 12 years of age and older

	A booster dose of Spikevax (0.25 mL, containing 50 micrograms mRNA, which is half of the primary dose) should be given intramuscularly to individuals 12 years of age and older at least 3 months after completion of the primary series. Spikevax may be used to boost individuals who have received a primary series with Spikevax or a primary series comprised of another mRNA vaccine or adenoviral vector vaccine.
Maximum Daily Dose Pediatrics*	N/A
Adjustment	There are no dosage adjustments provided in the manufacturer's labeling.
Prescribing edits*	AGE, PE
AGE (Age Edit)	The safety and efficacy of Spikevax in children less than 6 years of age have not yet been established. No data are available.
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)	N/A
ST (Step Therapy)	N/A
EU (Emergency Use Only)	N/A
PE (Protocol Edit)	**Primary Series:** Individuals 12 years of age and older: Spikevax is administered as a course of 2 (two) 100 microgram doses (0.5 mL each). **Severely immunocompromised aged 6 years and older:** A third dose may be given at least 28 days after the second dose to individuals 12 years of age and older (0.5 mL, 100 micrograms) **Booster dose:**

	Individuals 12 years of age and older A booster dose of Spikevax (0.25 mL, containing 50 micrograms mRNA, which is half of the primary dose) should be given intramuscularly to individuals 12 years of age and older at least 3 months after completion of the primary series.
SAFETY	
Main Adverse Drug Reactions (Most common and most serious)	**Most common:** Chills, arthralgia, diarrhea, fatigue, fever, nausea and vomiting. **Most serious:** Hypersensitivity reactions, myocarditis and pericarditis.
Drug Interactions*	**Category X:** Elivaldogene Autotemcel
Special Population	**Altered immunocompetence:** COVID-19 vaccines can be safely administered to immunocompromised persons (including those with HIV or receiving immunosuppressant therapy) if no contraindications exist; as with the general population, mRNA vaccines are preferred. Immunocompromised persons may have a diminished immune response to the vaccine, but the potential benefit of the vaccine outweighs the uncertainties. If possible, complete COVID-19 vaccination ≥2 weeks prior to initiation or resumption of immunosuppressive therapy. **Persons who had received dermal fillers:** Temporary swelling at or near the site of filler injection has been infrequently reported after COVID-19 (mRNA) vaccination. **Pediatric:** Multiple formulations from both manufacturers (Pfizer-BioNTech and Moderna) are available and the ages for which each product is

	authorized differs. Additionally, the recommended number of doses for some age groups may differ. Use extra caution when selecting formulation, dosage, and preparation prior to administration
Pregnancy	Vaccination of pregnant patients may be done in any setting authorized to administer the vaccine. The COVID-19 vaccine may be administered in any trimester and should be given as soon as possible to maximize maternal and fetal health. COVID-19 vaccines may be administered simultaneously with other vaccines routinely administered during pregnancy. Vaccination status should be documented for all pregnant patients; for patients who do not receive the COVID-19 vaccine, the discussion should be documented in the medical record and vaccination offered again at subsequent visits.
Lactation	The initiation of breastfeeding does not need to be avoided, and breastfeeding does not need to be discontinued in patients who are vaccinated.
Contraindications	History of a severe allergic reaction (eg, anaphylaxis) after a previous dose or to a component of the formulation.
Monitoring Requirements	Monitor for hypersensitivity and syncope for 15 minutes following administration. Observe patients for 30 minutes after vaccination in those patients with the following: a history of nonsevere, immediate (within 4 hours) allergic reaction after receipt of a COVID-19 vaccine; a history of anaphylaxis following receipt of a non–COVID-19 vaccine or injectable therapy; or a person with an allergy-related contraindication to a different type of

	COVID-19 vaccine. 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 (eg, 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 (eg, 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 (eg, 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. In general, it is recommended to defer vaccine administration in patients with moderate or severe acute febrile illness (with or without fever) and to provide vaccination in patients with mild acute illness (with or without fever). Although not included in the Pfizer or Moderna documentation from the FDA, the

	Canadian product information for the Pfizer vaccine recommends postponing vaccination in patients with acute severe febrile illness. In addition, the Canadian product information for the Moderna vaccine states to consider postponing vaccination in patients with acute severe febrile illness or severe acute infection. **Bleeding disorders:** Use with caution in patients with bleeding disorders (including thrombocytopenia); bleeding or 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. **Multisystem inflammatory syndrome:** In patients with a history of multisystem inflammatory syndrome (MIS), the benefits of vaccination are thought to outweigh the risks in patients who meet 2 recovery criteria: 1) clinical recovery from MIS (including return to baseline cardiac function) and 2) ≥90 days have passed since diagnosis. Vaccination can be considered in patients who do not meet both criteria on a case-by-case basis. In patients who developed MIS within 60 days following a dose of COVID-19 vaccine, decisions about subsequent doses should be made on a case-by-case basis. In patients who developed MIS >60 days after a previous dose of COVID-19 vaccine, subsequent doses should be considered ≥90 days after MIS diagnosis for patients who have clinically recovered (including return to baseline cardiac function). **Myocarditis/pericarditis:**

	Persons who experience myocarditis/pericarditis after a dose of the vaccine: For persons who developed myocarditis or pericarditis within 3 weeks after any dose of a COVID-19 vaccine, subsequent doses of any COVID-19 vaccine are generally not recommended. If after risk assessment a decision is made to administer subsequent dose(s), wait until complete resolution of signs/symptoms of myocarditis or pericarditis with no evidence of ongoing heart inflammation or sequelae as determined by clinical team. **Persons with history of myocarditis or pericarditis that occurred prior to vaccination or >3 weeks after a COVID-19 vaccine dose:** Persons with history of myocarditis or pericarditis that occurred prior to COVID-19 vaccination or >3 weeks after a COVID-19 vaccine dose may receive any FDA-approved or FDA-authorized COVID-19 vaccine after complete resolution of signs/symptoms of myocarditis or pericarditis with no evidence of ongoing heart inflammation or sequelae as determined by clinical team. This also applies to persons who had myocarditis or pericarditis due to SARS-CoV-2 or other viruses. **SARS-CoV-2 infection or exposure:** **Persons with history of COVID-19 or asymptomatic SARS-CoV-2 infection:** Vaccination is recommended for everyone ≥6 months of age (with an age-appropriate COVID-19 vaccine), regardless of history of symptomatic or asymptomatic SARS-CoV-2 infection. Persons who recently had SARS-CoV-2

	infection may consider delaying vaccine doses by 3 months from symptom onset or positive test (if asymptomatic); increased time between infection and vaccination may improve vaccination immune response. **Persons with current SARS-CoV-2 infection (including asymptomatic):** In persons with known current SARS-CoV-2 infection, defer vaccination until the person has recovered from acute illness (if symptomatic) and no longer requires isolation. **Persons with known SARS-CoV-2 exposure:** Persons with recent known exposure may be vaccinated if they do not have symptoms consistent with COVID-19 infection. Vaccination for postexposure prophylaxis is not recommended.
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), Canadian Agency for Drugs and Technologies in Health (CADTH), 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 Spikevax® COVID-19 Vaccine (mRNA).**

Table 26. Spikevax® HTA Analysis

MEDICATION	AGENCY	DATE – HTA RECOMMENDATION
Spikevax® COVID-19 Vaccine (mRNA)	NICE	Not available
	CADTH	Not available
	HAS[8]	Positive Recommendation – October 6, 2023 "**Favorable opinion on reimbursement** for active immunization to prevent COVID-19 caused by SARS-CoV-2, as part of primary vaccination and booster vaccination, in adults over 30 years of age, according to the current recommendations of the HAS."
	IQWIG	Not available
	PBAC	Not available

CONCLUSION STATEMENT – Spikevax® COVID-19 Vaccine (mRNA)

Spikevax® is a vaccine 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 modified messenger RNA (mRNA) in the vaccine is formulated in lipid particles that enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 spike (S) antigen. The vaccine elicits both neutralizing antibody and cellular immune responses to the S antigen, which protects against COVID-19 disease. It is given intramuscularly as a single 0.5ml dose. For individuals previously vaccinated with any COVID-19 vaccine, Spikevax® is to be administered at least 2 months after the last dose of the COVID-19 vaccine. Its use is backed by HAS as an HTA body. The use of Spikevax® is limited by its heightened risk of developing hypersensitivity reactions, myocarditis, and pericarditis.

2.1.2 Pneumococcal Vaccines

2.1.2.1 Vaxneuvance (Pneumococcal 15-Valent Conjugate Vaccine)

Table 27. 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)	B95.3
Drug Class	Vaccine
Drug Sub-class	Vaccine, Inactivated (Bacterial)
ATC Code	J07AL02
Pharmacological Class (ASHP)	Pneumococcal Conjugate Vaccine (15-Valent)
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 in adults 18 years of age and older.
Maximum Daily Dose Adults*	N/A
Dose (pediatrics)	Vaxneuvance® is to be administered as a 4-dose series at 2, 4, 6 and 12 through 15 months of age.
Maximum Daily Dose Pediatrics*	N/A
Adjustment	There are no dosage adjustments provided in the manufacturer's labeling.
Prescribing edits*	AGE, 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)	N/A
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 (eg, 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 (eg, 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 (eg, 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 (eg,

	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 (eg, 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), Canadian Agency for Drugs and Technologies in

Health (CADTH), 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 28. Vaxneuvance® HTA Analysis

MEDICATION	AGENCY	DATE – HTA RECOMMENDATION
Pneumococcal Conjugate Vaccine (15-Valent)	NICE	Not available
	CADTH	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.

2.2 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[24]:

Table 29. 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 worldwide manufacturing footprint. ACT-HIB® is registered on the NUPCO list. ACT-HIB® is a vaccine indicated for the prevention of invasive	There are no alternative agents on the SFDA. *Haemophilus Influenzae* Type B only exists as a part of combination vaccinations.

		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)

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 Comirnaty® (COVID-19 Vaccine, mRNA) – Pfizer

Comirnaty® was approved by the FDA in 2021 and by the EMA in 2022. 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 modified messenger RNA (mRNA) in the vaccine is formulated in lipid particles that enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 spike (S) antigen. The vaccine elicits both neutralizing antibody and cellular immune responses to the S antigen, which protects against COVID-19 disease. Comirnaty® is administered intramuscularly as a single dose of 0.3ml. For individuals previously vaccinated with any COVID-19 vaccine, the dose of Comirnaty® is to be administered at least 2 months after the last dose of COVID-19 vaccine.

2.4.1.2 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 Arexvy® (Respiratory Syncytial Virus Vaccine, Adjuvanted)

Arexvy® was approved by the FDA in May of 2023 and by the EMA in June of 2023. It is indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in individuals 60 years of age and older. Arexvy® promotes active immunization against respiratory syncytial virus prefusion F3 (RSVPre3) glycoprotein to protect against RSV-A and/or B-associated lower respiratory tract disease. The vaccine is an adjuvanted formulation, which has been shown to increase RSV-specific CD4+ T-cell frequencies. It is given intramuscularly as a single dose of 0.5ml.

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 Prevnar 20®

Prevnar 20® was initially approved by the FDA in 2021 and by the EMA in 2022. It is indicated for:

- Active immunization for the 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 in individuals 6 weeks of age and older.

- Active immunization for the prevention of otitis media caused by *S. pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F in individuals 6 weeks through 5 years of age.
- Active immunization for the 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 in individuals 18 years of age and older.

  It promotes active immunization against pneumonia and invasive disease 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, all of which are individually conjugated to CRM197 protein.

  It is given as a single dose of 0.5ml in adults 18 years of age and older.

Section 3.0 Key Recommendations Synthesis

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

Ages 12 Years and 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.
- Previously received 1 or more Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- Previously received 1 or more doses of Original monovalent Novavax vaccine, alone or in combination with any Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- Previously received 1 or more doses of Janssen vaccine, alone or in combination with any Original monovalent or bivalent mRNA vaccine or Original monovalent Novavax doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- 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:

Ages 12 Years and Older:

- Unvaccinated: 3 homologous (i.e., from the same manufacturer) updated (2023–2024 Formula) mRNA vaccine doses (i.e., Moderna, Pfizer-BioNTech) **OR** 2 updated (2023–2024 Formula) Novavax vaccine doses.
- Previously received 1 or 2 Original monovalent or bivalent mRNA vaccine doses: Complete the 3-dose series with 2 or 1 homologous updated (2023–2024 Formula) mRNA vaccine doses, respectively.
- Previously received a combined total of 3 or more Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- Previously received 1 or more Original monovalent Novavax vaccine doses, alone or in combination with any Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- Previously received 1 or more doses of Janssen vaccine, alone or in combination with any Original monovalent or bivalent mRNA vaccine or Original monovalent Novavax doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- Additional doses: May receive 1 or more additional doses of an updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) following the last recommended updated (2023–2024 Formula) COVID-19 vaccine dose.

4-Day Grace Period:

- Doses administered up to 4 days before the minimum interval, known as the 4-day grace period, are considered valid.

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:

Interchangeability of mRNA COVID-19 Vaccines:

- People aged 5 years and older who are moderately or severely immunocompromised should receive a 3-dose initial mRNA vaccination series using vaccines from the same manufacturer.

- For people who receive 1 Moderna and 1 Pfizer-BioNTech vaccine dose, the initial vaccination series is completed as follows:
    - People ages 6 months and older who are moderately or severely immunocompromised should follow the recommended 3-dose schedule. A third dose of either updated (2023–2024 Formula) Moderna vaccine or updated (2023–2024 Formula) Pfizer-BioNTech vaccine should be administered as follows:
        - Aged 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:

Adults:

- Local: Pain at the injection site; less commonly, redness and swelling
- Systemic: Fatigue, headache, and myalgia

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 muscle pain

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.
- 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.
- 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.

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[21]:

Table 30. 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.
    - 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.
- 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.

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.

  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.

  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.

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 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.

Newly Approved SFDA Registered Vaccinations:

- Spikevax® is a vaccine 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. It is given intramuscularly as a single 0.5ml dose. For individuals previously vaccinated with any COVID-19 vaccine, Spikevax® is to be administered at least 2 months after the last dose of the COVID-19 vaccine.
- 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.

Newly Approved Non-SFDA Registered Vaccinations:

- Comirnaty® 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. Comirnaty® is administered intramuscularly as a single dose of 0.3ml. For individuals previously vaccinated with any COVID-19 vaccine, the dose of Comirnaty® is to be administered at least 2 months after the last dose of COVID-19 vaccine.
- The Novavax vaccine 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. It is given intramuscularly as 0.5 mL per dose for 2 doses administered 3 to 8 weeks apart.
- Arexvy® is indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in individuals 60 years of age and older. It is given intramuscularly as a single dose of 0.5ml.
- PreHevbrio® 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. It is an injectable suspension, for intramuscular use supplied as a single-dose vial. A single dose of PreHevbrio® is 1.0 mL.
- MenQuadfi® is indicated for active immunization for the prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W, and Y. It is given intramuscularly as a single dose of 0.5ml.
- Penbraya® is indicated for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroups A, B, C, W, and Y. It is given intramuscularly as 2 doses (approximately 0.5 mL each) 6 months apart.
- Prevnar 20® is indicated for:
    - Active immunization for the 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 in individuals 6 weeks of age and older.
    - Active immunization for the 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 in individuals 18 years of age and older.

  It is given as a single dose of 0.5ml in adults 18 years of age and older.

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 (Sensitization, Immunologic[Title/Abstract])) OR (Sensitization, Immunological[Title/Abstract])) OR (Immunological Sensitization[Title/Abstract])) OR (Immunological Sensitizations[Title/Abstract])) OR (Sensitizations, Immunological[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 (Immunologic Sensitization[Title/Abstract])) OR (Stimulation, Immunologic[Title/Abstract])) OR (Variolation[Title/Abstract])) OR (Variolations[Title/Abstract])		Guideline, in the last 1 year	("vaccination"[MeSH Terms] OR "immunization"[MeSH Terms] OR "Immunizations"[Title/Abstract] OR "sensitization immunologic"[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	14

			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 "immunologic stimulation"[Title/Abstract] OR "Immunostimulation"[Title/Abstract] OR "immunological stimulation"[Title/Abstract] OR "immunological stimulations"[Title/Abstract] OR "stimulation 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 Fields] OR "stimulator s"[All Fields] OR "stimulators"[All Fields]) AND "Immunological"[Title/Abstract]) OR "immunologic	

			sensitization"[Title/Abstract] OR "stimulation immunologic"[Title/Abstract] OR "Variolation"[Title/Abstract] OR "Variolations"[Title/Abstract]) AND ((y_1[Filter]) AND (guideline[Filter]))	

Appendix D. Immunization Schedule Scheme

The following Vaccination Scheme was opted from the 2023 CDC Immunization Schedule for Adults[15]:

Legend

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection	Recommended vaccination for adults with an additional risk factor or another indication	Recommended vaccination based on shared clinical decision-making	No recommendation/Not applicable

Vaccine	19-26 years	27-49 years	50-64 years	≥65 years
COVID-19	2- or 3- dose primary series and booster (see notes)			
Influenza inactivated (IIV4) or Influenza recombinant (RIV4)	1 dose annually			
or Influenza live attenuated (LAIV4)		or 1 dose annually		
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management (see notes)			
	1 dose Tdap, then Td or Tdap booster every 10 years			
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)			For healthcare personnel, (see notes)
Varicella (VAR)	2 doses (if born in 1980 or later)		2 doses	
Zoster recombinant (RZV)	2 doses for immunocompromising conditions (see notes)		2 doses	
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years		
Pneumococcal (PCV15, PCV20, PPSV23)	1 dose PCV15 followed by PPSV23 OR 1 dose PCV20 (see notes)			See Notes
				See Notes
Hepatitis A (HepA)	2, 3, or 4 doses depending on vaccine			
Hepatitis B (HepB)	2, 3, or 4 doses depending on vaccine or condition			
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication, see notes for booster recommendations			
Meningococcal B (MenB)	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations			
	19 through 23 years			
Haemophilus influenzae type b (Hib)	1 or 3 doses depending on indication			

MMR for healthcare 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

Zoster recombinant:

2-dose series recombinant zoster vaccine (RZV, Shingrix) 2–6 months apart (minimum interval: 4 weeks; repeat dose if administered too soon). For detailed information, see www.cdc.gov/shingles/vaccination/immunocompromised-adults.html

Tdap in pregnancy:

1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36.

Pneumococcal vaccination:

- Age 65 years or older who have:
    - Not previously received a dose of PCV13, PCV15, or PCV20 or whose previous vaccination history is unknown: 1 dose PCV15 OR 1 dose PCV20.
        - 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 PPSV23.
        - If PCV20 is selected, administer at least 1 year after the last PCV13 dose.
        - If PPSV23 is selected, administer at least 1 year after the last PCV13 dose (may use minimum interval of 8 weeks for adults with an immunocompromising condition,* cochlear implant, or cerebrospinal fluid leak).
    - Previously received only PPSV23: 1 dose PCV15 OR 1 dose PCV20. Administer either PCV15 or PCV20 at least 1 year after the last PPSV23 dose.
        - If PCV15 is used, no additional PPSV23 doses are recommended.
    - Previously received both PCV13 and PPSV23 but NO PPSV23 was received at age 65 years or older: 1 dose PCV20 OR 1 dose PPSV23.
        - If PCV20 is selected, administer at least 5 years after the last pneumococcal vaccine dose.
        - If PPSV23 is selected, see dosing schedule at cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf.
    - 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 at least 5 years after the last pneumococcal vaccine dose.
- Age 19–64 years with certain underlying medical conditions or other risk factors** who have:

- Not previously received a PCV13, PCV15, or PCV20 or whose previous vaccination history is unknown: 1 dose PCV15 OR 1 dose PCV20.
    - 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
- Previously received only PCV13: 1 dose PCV20 OR 1 dose PPSV23.
    - If PCV20 is selected, administer at least 1 year after the PCV13 dose.
    - If PPSV23 is selected, see dosing schedule at cdc.gov/vaccines/vpd/pneumo/downloads/ pneumo-vaccine-timing.pdf
- Previously received only PPSV23: 1 dose PCV15 OR 1 dose PCV20. Administer either PCV15 or PCV20 at least 1 year after the last PPSV23 dose.
    - If PCV15 is used, no additional PPSV23 doses are recommended.
- Previously received PCV13 and 1 dose of PPSV23: 1 dose PCV20 OR 1 dose PPSV23.
    - If PCV20 is selected, administer at least 5 years after the last pneumococcal vaccine dose.
    - If PPSV23 is selected, see dosing schedule at cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

- For guidance on determining which pneumococcal vaccines a patient needs and when, please refer to the mobile app which can be downloaded here: cdc.gov/vaccines/vpd/pneumo/hcp/pneumoapp.html

**: Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiencies, iatrogenic immunosuppression, generalized malignancy, HIV infection, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplant, congenital or acquired asplenia, or 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 infection, Hodgkin disease, immunodeficiencies, iatrogenic immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic syndrome, solid organ transplant, or sickle cell disease or other hemoglobinopathies.*