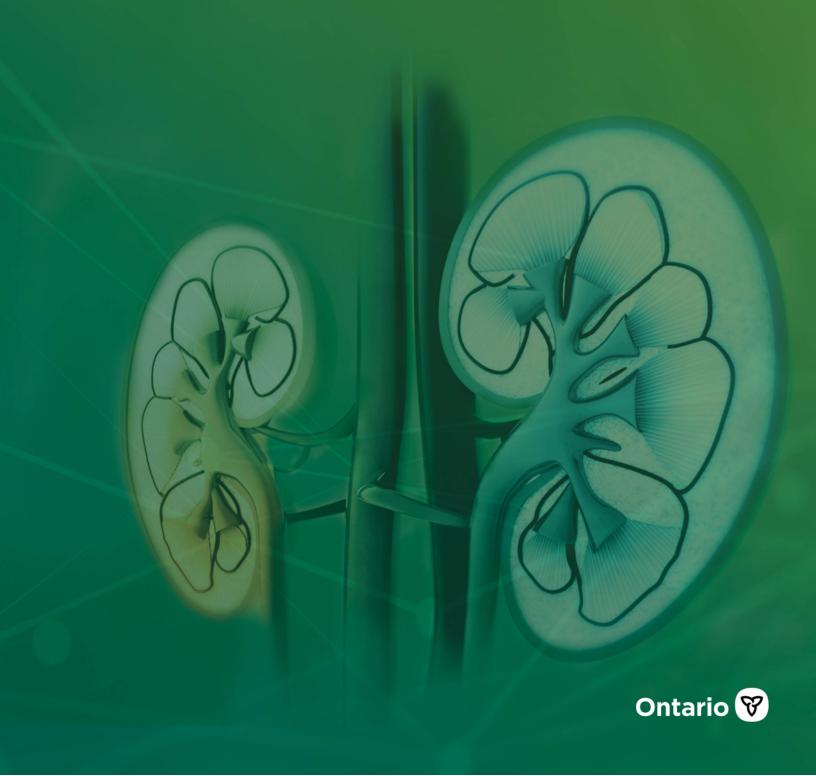


Considerations for Immunization

For adult patients with glomerulonephritis



Disclaimer

The information contained herein ("Information") is intended for informational purposes only, and no warranty as to its accuracy is provided or implied. The Information was collected from third party sources and Cancer Care Ontario makes no warranty that the Information is current. The Information is **intended for use by healthcare professionals to provide advice and recommendations about immunizations in patients with glomerulonephritis (GN) being initiated on or treated with immunosuppression**. Do not act or rely upon the Information without exercising your independent judgment or seeking the advice of a qualified professional. Anyone using the Information does so at his or her own risk.

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Contents

Disclaimer	
Acknowledgments	2
Resource Development	5
Vaccinations for Adults with Glomerulonephritis (GN)	5
General Principles	5
Immunization Specific Recommendations	6
Considerations For Immunization Of Patients Receiving Eculizumab (Soliris®)	11
Recommended Meningococcal Vaccines	11
Immunization Specific Recommendations	13
Travel Vaccines	15
References	16

Version 1 – September 2019



Resource Development

The information contained in this resource was derived from published evidence and clinical expert opinion.

Vaccinations for Adults with Glomerulonephritis (GN)

Relative to the immunocompetent patient population, GN patients are at increased risk for infection. GN patients with **at least one** of the following circumstances should be considered for immunization:

- Current proteinuria greater than 3 grams per day or nephrotic syndrome
- May start immunosuppressant therapy²
- Receiving immunosuppressant therapy²

General Principles

- 1. Vaccine immunogenicity decreases with increasing proteinuria, treatment with immunosuppressant therapy, and decreased kidney function.^{1,2}
- 2. Up-to-date routine immunizations, including the annual influenza vaccine, are recommended for GN patients, household members, and other close contacts.^{1,2}
- 3. GN patients taking immunosuppressant medication should not receive any **live** vaccines due to risk of disease caused by the live strain (examples provided below).²

Please refer to the Canadian Immunization Guide: Part 13 for most up-to-date list of live vaccines.

- Bacille Calmette-Guérin (BCG) Vaccine
- Herpes zoster (ZOSTAVAX®)
- Influenza (FLUMIST®)
- Measles, Mumps, Rubella (MMR[®] II, PRIORIX[®])
- Measles, Mumps, Rubella, Varicella (PRIORIX-TETRA®, PROQUAD™)
- Rotavirus (ROTARIX[®], RotaTeq[®])
- Oral typhoid (VIVOTIF®)
- Varicella (VARILRIX®, VARIVAX® III)
- Yellow fever (YF-VAX®)
- 4. Immunization and immunosuppressant therapy:
 - If immunization cannot be completed prior to initiating immunosuppressant therapy, a period of at least three months should elapse between therapy cessation and the administration of inactivated vaccines (if possible, to ensure maximum immunogenicity) or live vaccines (to reduce the risk of disease caused by the vaccine strain).²
 - Consider vaccination with inactivated vaccines during immunosuppressant therapy, for those with a long projected duration of immunosuppression and high risk of acquisition for disease based on exposure risk.
- 5. Immunization **post-corticosteroid** therapy:
 - Immunization can occur as early as 4 weeks following discontinuation of high-dose systemic steroid therapy.²
 - Corticosteroid therapy is not a contraindication to immunization when steroid therapy is short-term (i.e. less than 14 days); or a low-to-moderate dose of prednisone or equivalent (less than 20 mg/day); or long-term, alternate-day treatment with short-acting preparations; or maintenance physiologic replacement therapy; or administered topically, inhaled or locally injected (e.g. joint injection).²



6. Immunization post-rituximab therapy:

 If immunization cannot be completed prior to initiation of rituximab, generally a period of 6-12 months should elapse between rituximab cessation and the administration of inactivated or live vaccines. B cell enumeration should be reviewed prior to immunization.²

Immunization Specific Recommendations

1. Pneumococcal vaccine^{1,2,4,5}

Prevnar[™]13 (PCV13) 0.5 mL IM (Pneumococcal conjugate13 valent [Pneu-C-13])

Pneumovax®23 (PPSV23) 0.5 mL IM (Pneumococcal polysaccharide 23 valent [Pneu-P-23])

Recommended^{5,6}

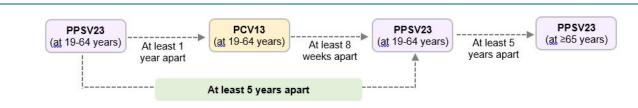
- Administer Prevnar[™]13 as early as possible or at least 2 weeks prior to immunosuppressant start, but can still vaccinate post-immunosuppressant start
- Administer Pneumovax[®]23 at least 8 weeks after receiving Prevnar[™]13
- Booster with Pneumovax[®]23 if greater than 5 years after receiving first Pneumovax[®]23
- Booster again with Pneumovax[®]23 at age 65 years if at least 5 years apart from last Pneumovax[®]23



'Pneumococcal Vaccine Timing for Adults', adapted from Centers for Disease Control and Prevention⁶ (p.4)

If prior immunization with Pneu-P-23^{5,6}

- Administer Prevnar[™]13 at least 1 year after having first received Pneumovax[®]23
- Booster with Pneumovax®23 if greater than 5 years after receiving last Pneumovax®23, but separate at least 8 weeks after receiving Prevnar™13
- Booster again with Pneumovax[®]23 at age 65 years if at least 5 years apart from last Pneumovax[®]23



'Pneumococcal Vaccine Timing for Adults', adapted from Centers for Disease Control and Prevention⁶ (p.4)



Cost of Pneumococcal Vaccine in Ontario

Vaccine	Cost (CAD) *
Prevnar™13	\$107.29
Pneumovax®23	\$24.09

^{*}Estimated retail cost based on average distributor prices in Ontario in February 2018 (subject to change).

For more information on public funding criteria, please refer to the **Publicly Funded Immunization Schedules for Ontario**.⁷

2. Inactivated Influenza vaccine^{1,2,4,8}

- Inactivated influenza vaccine should be given annually during influenza season.
- Those receiving anti-B cell antibodies may be less likely to respond and clinical judgment may be used in recommending influenza vaccination to this patient group.
- Close contacts should be encouraged to get vaccinated.
- There may be special considerations regarding influenza vaccination for those 65 years or older. Please refer to yearly recommendations on selection of vaccine for this patient population.

3. Varicella vaccine (Chicken pox)

Varilrix[®] 0.5 mL SC (Live attenuated virus)

Varivax®III 0.5 mL SC (Live attenuated virus)

- If history of chicken pox, do not vaccinate.
- If no history of chicken pox, vaccinate as early as possible or at least 4 weeks prior to immunosuppressant start to reduce risk of disease caused by the vaccine strain.²
- Do not administer if immunosuppression has been initiated as both Varivax[®]III and Varilrix[®] are live vaccines.^{2,9,10,11}

Normal Renal Function	Chronic Kidney Disease
 Varilrix®: Administer at week 0 and week 69 Varivax®III: Administer at week 0 and week 4-810 	Administer at months 0 and > 3 ¹¹

Cost of Varicella Vaccine in Ontario

Vaccine	Cost (CAD)*
Varilrix [®]	\$70.60
Varivax [®] III	\$85.89

^{*}Estimated retail cost based on average distributor prices in Ontario in February 2018 (subject to change).

For more information on public funding criteria, please refer to the <u>Publicly Funded Immunization Schedules</u> <u>for Ontario</u>.⁷

4. Herpes zoster vaccine (Shingles)

Shingrix® 0.5 mL IM (non-live recombinant zoster vaccine)

- Shingrix® is not a live vaccine and is the preferred vaccine over the live herpes zoster vaccine (Zostavax®).
- Recommended for patients 50 years of age and older. 12,13
- Immunocompromised individuals may be considered on a case-by-case assessment of the benefits versus risks. 13
- Administer at month 0 and month 2-6.¹²



- Ideally vaccinate as early as possible or at least 2 weeks prior to immunosuppressant start, but can still vaccinate post-immunosuppressant start.^{2,13}
- Two doses of vaccine are necessary regardless of prior history of herpes zoster infection or prior receipt of Zostavax[®]. ^{12,13}
- Herpes zoster infection can recur. If a patient experienced an episode of herpes zoster, vaccination should be delayed until at least 1 year after the herpes zoster episode.¹³
- Individuals previously vaccinated with Zostavax[®] should be re-vaccinated with 2 doses of Shingrix[®] at least 1 year after receiving Zostavax[®].
- Shingrix® was demonstrated to be more than 90% effective at preventing shingles for at least the first 4 years after vaccination. 12,13
- There is no current recommendation for booster doses of Shingrix[®]. It is not known whether booster doses are beneficial. This is an area of ongoing research.¹³

Varicella versus herpes zoster immunization

- Herpes zoster vaccine should be administered to individuals indicated for vaccine regardless of varicella infection history.¹³
- There is no known safety risk associated with vaccination of healthy individuals who are susceptible to varicella.¹³
- If a diagnosis of varicella cannot be recalled, routine testing of adults aged 50 years and older for varicella antibody prior to immunization is not recommended.¹³

Cost of Herpes Zoster Vaccine in Ontario

Vaccine	Cost (CAD)*
Shingrix [®]	\$139.99

^{*}Estimated retail cost based on average distributor prices in Ontario in February 2018 (subject to change).

For more information on public funding criteria, please refer to the Publicly Funded Immunization Schedules for Ontario.7

5. Hepatitis B (HB) vaccine (Recombinant monovalent hepatitis B)¹

HB serology should be known and ideally HB immunity attained prior to initiation of immunosuppressant therapy as immunosuppression can reactivate HB virus (HBV) in infected patients.

HB serology:

HB surface antibody	(HBsAb)
HB surface antigen	(HBsAg)
HB core antibody	(HBcAb)

If acquired natural HBV immunity: (HBsAb positive, HBcAb positive, HBsAg negative)

No further serological testing/immunizations required.¹⁴



If not previously immunized against HBV

- Ideally vaccinate as early as possible or at least 2 weeks prior to immunosuppressant start, but can still vaccinate post-immunosuppressant start.²
- Vaccine efficacy can vary depending on degree of immunosuppression.
- Engerix®-B and Recombivax®-HB vaccines may be used interchangeably.¹⁴
- Combined hepatitis A and HB vaccine, Twinrix[®], should not be used in this patient population due to higher dose HB vaccine requirements unless Twinrix[®] is administered with an additional HB 20 mcg IM vaccine.
- Post-immunization serologic testing 1 to 6 months after completion of the vaccine series is recommended.¹⁴
- If HBsAb positive (titre greater than 10 IU/L consistent with immunity status), check HBsAb annually as immunity can be lost if immunocompromised.¹⁴

18 and 19 years of age¹⁴

Engerix®-B

40 mcg (2 mL) IM at months 0, 1, 2 and 6

(Single Engerix®-B 40 mcg vial does not exist. Give 2 x 20 mcg (1 mL) vial for 40 mcg (2 mL) dose.)

OR

Recombivax®-HB

10 mcg (1 mL) IM at months 0, 1 and 6

20 years of age and older¹⁴

Engerix ®-B

40 mcg (2 mL) IM at months 0, 1, 2 and 6

(Single Engerix®-B 40 mcg vial does not exist. Give 2 x 20 mcg (1 mL) vial for 40 mcg (2 mL) dose.)

OR

Recombivax®-HB

40 mcg (1 mL) IM at months 0, 1 and 6

If a protective antibody concentration is not present:

- Individuals who do not develop HBsAb titre of at least 10 IU/L after the first series of immunizations should receive a second series.¹⁴
- Additional vaccine doses (up to 3 doses if administering Recombivax®-HB or up to 4 doses if administering Engerix®-B) received in a second immunization series will produce a protective antibody response in 50% to 70% of healthy adults who did not initially respond to the vaccine.¹⁴
- Serology should be rechecked within 1 to 6 months after the second series.¹⁴
- Individuals who fail to respond to a second series are unlikely to benefit from further immunization and should be counselled on alternative risk reduction measures.¹⁴

Cost of Hepatitis B Vaccines in Ontario

Vaccine	Cost (CAD)*
Engerix®-B 20 mcg x 2 vials = 40 mcg	\$26.09 x 2 vials = \$52.18
Recombivax®-HB 40 mcg	\$211.99

^{*}Estimated retail cost based on average distributor prices in Ontario in February 2018 (subject to change).

For information on public funding criteria, please refer to the Publicly Funded Immunization Schedules for Ontario.⁷



6. Human Papillomavirus vaccine (HPV)

Gardisil®9 0.5 mL IM (Human papillomavirus 9 valent recombinant vaccine)

- All males aged 9 to 26 and females aged 9 to 45, should be considered for vaccination if at risk of ongoing sexual exposure.¹⁵
- Administer at months 0, 2 and 6.¹⁵
- Gardisil®9 is not a live vaccine so it can be administered to patients taking immunosuppressant medication.¹⁵
- Ideally vaccinate as early as possible or at least 2 weeks prior to immunosuppressant start, but can still vaccinate post-immunosuppressant start.²

Cost of HPV Vaccine in Ontario

Vaccine	Cost (CAD)*
Gardisil [®] 9	\$199.73

^{*}Estimated retail cost based on average distributor prices in Ontario in February 2018 (subject to change).

For more information on public funding criteria, please refer to the <u>Publicly Funded Immunization Schedules</u> for Ontario.⁷



CONSIDERATIONS FOR IMMUNIZATION OF PATIENTS RECEIVING ECULIZUMAB (SOLIRIS°)

Eculizumab (Soliris®) is indicated for the treatment of:

 Atypical hemolytic uremic syndrome (atypical HUS) to reduce complement-mediated thrombotic microangiopathy (TMA)¹⁶

Eculizumab inhibits terminal complement activation; therefore, patients may have increased susceptibility to infections, especially with Neisseria and encapsulated bacteria.¹⁶

Eculizumab increases patient susceptibility to meningococcal infection (*Neisseria meningitidis*). Meningococcal disease due to any serogroup may occur. The manufacturer has issued a black box warning that cases of serious or fatal meningococcal infections have been reported in eculizumab-treated patients.

Recommended Meningococcal Vaccines

All patients must be vaccinated against meningococcal infections prior to, or at the time of, initiating eculizumab therapy. Serogroup B meningococcal vaccine should be administered in addition to meningococcal quadrivalent conjugate vaccine.¹⁶

Monovalent conjugate meningococcal vaccine (Men-C-C) should not be used in this setting due to the high risk of meningococcal infection and the need for multiple meningococcal serotype coverage.

Vaccination, particularly with a vaccine against serogroup B meningococcal infection, may further activate complement. So patients with aHUS may have a worsening of their clinical symptoms (e.g. TMA complications). Patients should be closely monitored for their disease symptoms post-vaccination.¹⁶

1. Meningococcal quadrivalent conjugate vaccine (Men-C-ACYW-135) 16

Menactra® 0.5 mL IM (Men-C-ACYW-DT)

OR

Menveo[™] 0.5 mL IM (Men-C-ACYW-CRM)

OR

Nimenrix[™] 0.5 mL IM (Men-C-ACYW-TT)

- Administer IM at weeks 0 and 8¹⁷
- Administer booster dose every 5 years while receiving eculizumab¹⁷
- Menactra[®], Menveo[®], and Nimenrix[®] vaccines may be used interchangeably¹⁷



Considerations for Immunization of Patients Receiving Eculizumab (Soliris®) – Continued

2. Serogroup B Meningococcal vaccine¹⁶

Bexsero® 0.5 mL IM (Multicomponent serogroup B [4CMenB])

- Vaccination may further activate complement and patients may experience increased symptoms of their underlying disease. Therefore, the product monograph suggests vaccinating only when the underlying complement mediated disease is clinically controlled with eculizumab.¹⁶ However, clinicians may decide to vaccinate if concern for meningococcal infection risk is greater.
- Administer IM at 0 and 4 weeks.¹⁷
- The need for and timing of serogroup B vaccine booster doses has not yet been determined.¹⁷
- Trumenba[™] is an alternative serogroup B vaccine that is available in Canada but we await National
 Advisory Committee on Immunization (NACI) dosing and schedule recommendations for this product in the
 immunocompromised population.

Cost of Meningococcal Multicomponent Vaccine in Ontario

Vaccine	Cost (CAD)*
Menactra®	\$115.89
Menveo®	\$119.39
Nimenrix™	\$127.95
Bexsero®	\$118.79

^{*}Estimated retail cost based on average distributor prices in Ontario in February 2018 and May 2019 for Nimenrix (subject to change).

For more information on public funding criteria, please refer to the <u>Publicly Funded Immunization Schedules</u> <u>for Ontario</u>.⁷

3. Recommended Antibiotic Prophylaxis

- The manufacturer notes that vaccination may not prevent all meningococcal infections.¹⁶
- Patients who initiate eculizumab treatment less than 2 weeks after receiving a meningococcal vaccine must receive antibiotic prophylaxis until 2 weeks after vaccination.¹⁶
- Antibiotic prophylaxis should be offered to all patients for the duration of eculizumab treatment ¹⁹ and for 4 weeks after last eculizumab dose to potentially reduce the risk for meningococcal disease.²⁰
- All patients should be monitored for early signs and symptoms of meningococcal infection. Patients should be informed to seek medical care immediately if they experience any of the following symptoms while they are receiving eculizumab and for up to 3 months after last dose of eculizumab:²¹
 - headache with nausea or vomiting
 - headache with fever
 - headache with stiff neck or stiff back
 - o fever +/- rash
 - o confusion
 - o muscle aches with flu-like symptoms
 - o eve sensitivity to light
- Discontinue eculizumab in patients who are undergoing treatment for serious meningococcal infection.



NB: Patients enrolled in the **One Source™ Treatment Support Program** are eligible for financial assistance and at home administration of the quadrivalent conjugate and the serotype B meningococcal vaccines.

Considerations for Immunization of Patients Receiving Eculizumab (Soliris®) – Continued

Recommended

Penicillin VK 300 mg PO BID for duration of eculizumab therapy and for 4 weeks after last eculizumab dose

If allergy to penicillin

Azithromycin 500 mg PO once daily for duration of eculizumab therapy and for 4 weeks after last eculizumab dose

OR

Ciprofloxacin 500 mg PO twice daily for duration of eculizumab therapy and for 4 weeks after last eculizumab dose

Immunization Specific Recommendations

The following immunizations are recommended for patients with an acquired complement deficiency who may start or are already receiving the terminal complement inhibitor, eculizumab.

4. Haemophilus influenza type b conjugate vaccine

Act-HIB® 0.5 mL IM (Hib)

OR

Hiberix® 0.5 mL IM (Hib)

 Administer as early as possible (and at least 1 year after any previous dose) ²², but can still vaccinate posteculizumab start

Cost of Haemophilus influenza type b conjugate vaccine in Ontario

Vaccine	Cost (CAD)*
Act-HIB®	\$49.72
Hiberix [®]	\$44.29

^{*}Estimated retail cost based on average distributor prices in Ontario in February 2018 (subject to change).

For more information on public funding criteria, please refer to the <u>Publicly Funded Immunization Schedules</u> for Ontario.⁷



Considerations for Immunization of Patients Receiving Eculizumab (Soliris®) – Continued

5. Pneumococcal vaccine

Prevnar[™]13 0.5 mL IM (Pneumococcal conjugate13 valent [Pneu-C-13])

Pneumovax®23 0.5 mL IM (Pneumococcal polysaccharide 23 valent [Pneu-P-23])

Recommended^{5,6}

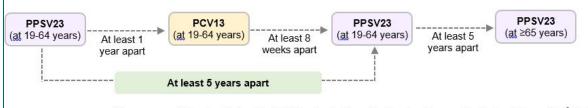
- Administer Prevnar[™]13 as early as possible or at least 2 weeks prior to immunosuppressant start, but can still vaccinate post-immunosuppressant start
- Administer Pneumovax[®]23 at least 8 weeks after receiving Prevnar[™]13
- Booster with Pneumovax[®]23 if greater than 5 years after receiving first Pneumovax[®]23
- Booster again with Pneumovax[®]23 at age 65 years if at least 5 years apart from last Pneumovax[®]23



'Pneumococcal Vaccine Timing for Adults', adapted from Centers for Disease Control and Prevention⁶ (p.4)

If prior immunization with Pneu-P-23^{5,6}

- Administer Prevnar[™]13 at least 1 year after having first received Pneumovax[®]23
- Booster with Pneumovax[®]23 if greater than 5 years after receiving last Pneumovax[®]23, but separate at least 8 weeks after receiving Prevnar[™]13
- Booster again with Pneumovax[®]23 at age 65 years if at least 5 years apart from last Pneumovax[®]23



'Pneumococcal Vaccine Timing for Adults', adapted from Centers for Disease Control and Prevention⁶ (p.4)

Cost of Pneumococcal Vaccine in Ontario

Vaccine	Cost (CAD) *
Prevnar™13	\$107.29
Pneumovax [®] 23	\$24.09

^{*}Estimated retail cost based on average distributor prices in Ontario in February 2018 (subject to change).

For more information on public funding criteria, please refer to the **Publicly Funded Immunization Schedules for Ontario**.⁷



Travel Vaccines

1. Are travel vaccines necessary?

Immunizations to protect travellers can be life-saving and are a cornerstone of travel health protection.

2. When should I start thinking about getting travel vaccines?

A travel health clinic or healthcare provider should be consulted as early as possible, ideally *at least* 4 to 6 weeks in advance of travel, to provide sufficient time for completion of optimal immunization schedules.

3. What vaccines should I consider getting before travelling?

Immunizations related to travel can be categorized as:

- Routine: part of the recommended primary series of immunizations or booster doses
- **Required:** may be a requirement of international law or proof of immunization may be considered a visa requirement
- **Recommended:** based on a risk assessment of the travel itinerary, the nature of travel, and the traveller's underlying health for maintenance of health while travelling

For more information on specific travel vaccine recommendations, please refer to the <u>Public Health Agency of Canada</u>. Canadian Immunization Guide, Part 3: Immunization of Travellers.²³

4. What else can I do to protect myself while travelling?

The following protective measures are essential for health protection while travelling and are complementary to immunization:

- Sanitation and hygiene
- Food precautions
- Insect or animal bite prevention
- Injury prevention

5. Where can I find more information about travel vaccines?

- Visit a travel health clinic for review of immunizations and travel medications based on age, travel location, planned travel activities, and local conditions
- Government of Canada's Travel Vaccines (Find vaccines recommended by destination) https://travel.gc.ca/travelling/health-safety/vaccines
- A Canadian's Guide to Healthy Travel Abroad webpage https://travel.gc.ca/travelling/health-safety/vaccines
- World Health Organization (WHO)

https://www.who.int/ith/ith-country-list.pdf?ua=1



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