**Regimen Monograph**



## A - Regimen Name

# VENE+RITU Regimen

**Venetoclax - Rituximab**

**Disease Site**

Hematologic
Leukemia - Chronic Lymphocytic (CLL)

**Intent**

Palliative

**Regimen Category**

**Evidence-Informed :**

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

**Rationale and Uses**

For the treatment of adult patients with CLL with ECOG status 0-2, who have received at least one prior therapy, irrespective of their 17p deletion status

(Refer to NDFP and EAP criteria)

**Supplementary Public Funding**

**venetoclax**
Exceptional Access Program (venetoclax - Treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) according to clinical criteria)

**riTUXimab**
New Drug Funding Program (Rituximab (Biosimilar IV) and Rituximab SC - In Combination with Venetoclax - Relapsed Chronic Lymphocytic Leukemia)

(NDFP Website )

**riTUXimab (subcut)**
New Drug Funding Program (Rituximab (Biosimilar IV) and Rituximab SC - In Combination with Venetoclax - Relapsed Chronic Lymphocytic Leukemia)
(NDFP Website )

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## B - Drug Regimen

**Note:** Different rituximab products are NOT INTERCHANGEABLE.

**Venetoclax dose ramp-up period (5 weeks total):**

| | | | |
|---|---|---|---|
| **venetoclax** | 20 mg | PO | Daily x 1 week |
| **venetoclax** | 50 mg | PO | Daily x 1 week |
| **venetoclax** | 100 mg | PO | Daily x 1 week |
| **venetoclax** | 200 mg | PO | Daily x 1 week |
| **venetoclax** | 400 mg | PO | Daily x 1 week |

**Start rituximab after the patient has received venetoclax 400 mg daily for 7 days.**

**Cycle 1: All patients must receive their first dose of rituximab by IV infusion.**

| | | | |
|---|---|---|---|
| **riTUXimab** | 375 mg /m² | IV | Day 1 |
| **venetoclax** | 400 mg | PO | Daily |

**Cycles 2 to 6:**

**Rituximab IV:**

| | | | |
|---|---|---|---|
| **riTUXimab** | 500 mg /m² | IV | Day 1 |

OR

**Rituximab Subcutaneous:**

**The subcutaneous formulation must only be given at the second or subsequent cycles, and only after at least 1 full rituximab IV dose.**

| | | | |
|---|---|---|---|
| **riTUXimab (subcut)** | 1600 mg | Subcut | Day 1 |

**Plus VENE Treatment:**

| | | | |
|---|---|---|---|
| **venetoclax** | 400 mg | PO | Daily |

**See VENE(MNT) for Cycles 7 and beyond**

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## C - Cycle Frequency

**Rituximab**: REPEAT EVERY 28 DAYS for a usual total of 6 cycles unless disease progression or unacceptable toxicity occurs.

**Venetoclax**: CONTINUE for a total of 24 months (from start of rituximab), unless disease progression or unacceptable toxicity occurs.

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## D - Premedication and Supportive Measures

**Antiemetic Regimen:** Minimal

Also refer to CCO Antiemetic Recommendations.

**Extravasation Potential:** None

**Pre-medication (prophylaxis for infusion reactions):**

- Administer at least 30 minutes prior to rituximab:

- Oral antipyretic (e.g. acetaminophen)
- H1-receptor antagonist (e.g. diphenhydramine)
- Corticosteroid (e.g. methylprednisolone 80 mg IV) in patients with high bulk disease or pulmonary involvement if no corticosteroids are already being given as part of the chemotherapy regimen.
- In patients receiving **subcut rituximab** who experienced adverse effects with pre-medications, the omission of pre-medications can be considered.

**Other supportive care:**

- **Screen for hepatitis B virus in all cancer patients starting systemic treatment.** Refer to the hepatitis B virus screening and management guideline.
- Consider supportive measures such as antimicrobials for signs of infection, and prophylactic use of G-CSF according to local guidelines.
- **Tumour lysis prophylaxis** (i.e. adequate hydration and anti-hyperuricemic agents) prior to and during ramp-up phase **is required for all patients**.

Prophylaxis for TLS:

| **Tumour Burden** | | **Prophylaxis** | | **Blood Chemistry Monitoring[c,d]** |
|---|---|---|---|---|
| | | **Hydration[a]** | **Anti-hyperuricemics[b]** | **Setting and Frequency of Assessments** |
| Low | All LN < 5 cm<br><br>AND<br><br>ALC < 25 x $10^9$/L | Oral (1.5 to 2 L) | Allopurinol | Outpatient:<br>• Pre-dose, 6 to 8 hours, 24 hours at first dose of 20 mg and 50 mg<br>• Pre-dose at subsequent ramp-up doses, and post-dose at clinical discretion |
| Medium | Any LN 5 cm to < 10 cm<br><br>OR<br><br>ALC ≥ 25 x $10^9$/L | Oral (1.5 to 2 L) and consider additional IV | Allopurinol | Outpatient:<br>• Pre-dose, 6 to 8 hours, 24 hours at first dose of 20 mg and 50 mg<br>• Pre-dose at subsequent ramp-up doses, and post- |

| | | | | |
|---|---|---|---|---|
| | | | | dose at clinical discretion<br>• Consider hospitalization if CrCl < 80 mL/min at first dose of 20 mg and 50 mg; see below |
| High | Any LN ≥ 10 cm<br><br>OR<br><br>ALC ≥ 25 x $10^9$/L AND any LN ≥ 5 cm | Oral (1.5 to 2 L) and IV (150 to 200 mL/hr, as tolerated) | Allopurinol; consider rasburicase if elevated uric acid at baseline | In hospital at first dose of 20 mg and 50 mg<br><br>• Pre-dose, 4, 8, 12 and 24 hours<br><br>Outpatient at subsequent ramp-up doses<br><br>• Pre-dose, 6 to 8 hours, 24 hours |

ALC= absolute lymphocyte count; LN= lymph node
a. Start oral hydration 2 days before and continue during ramp-up. Administer IV hydration if unable to tolerate oral.
b. Start allopurinol or xanthine oxidase inhibitor for 2-3 days prior to starting venetoclax.
c. Evaluate blood chemistries (potassium, phosphorus, uric acid, calcium, creatinine); review in real time.
d. For patients at continued risk of TLS, monitor blood chemistries at 6 to 8 hours and at 24 hours at each subsequent ramp-up dose.

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## E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated.

Correct potassium, uric acid, phosphorus, calcium, and creatinine abnormalities prior to initiation.

Concomitant use of venetoclax with strong CYP3A4 inhibitors is **contraindicated during initiation and ramp-up phase**. Also refer to Section G - Interactions for dosing when venetoclax is co-administered with CYP3A4 or P-gp inhibitors.

See premedication and monitoring sections for supportive care, screening and monitoring recommendations.

Since transient hypotension may occur during rituximab infusion, consideration should be given to withhold antihypertensive medication 12 hours prior to and throughout the rituximab infusion.

**Dosage with toxicity**

Venetoclax: For dose interruptions that last:

- > 1 week during first 5 weeks of ramp-up, or
- > 2 weeks after completing ramp-up,

Reassess for risk of TLS to determine if dose reduction is necessary.

| Venetoclax Dose at Interruption (mg/day) | Venetoclax Restart Dose (mg/day)[a] |
|---|---|
| 400 | 300 |
| 300 | 200 |
| 200 | 100 |
| 100 | 50 |
| 50 | 20 |
| 20 | 10 |

a. Continue the reduced dose for 1 week before increasing the dose during ramp-up.

| Toxicity/Event | Venetoclax Dose* | Rituximab (IV or subcut) Dose** |
|---|---|---|
| Blood chemistry suggests TLS | Hold next day's dose.<br><br>If resolved within 24-48 hours; resume at same dose. | Hold; resume at same dose. |
| Clinical TLS or blood chemistry changes for ≥ 48 hours | Hold until resolved; resume at a reduced dose (see table above) and follow TLS prophylaxis. | |
| Any Grade 3 or 4 non-hematological<br>≥ Grade 3 neutropenia*** with infection or fever<br>Grade 4 hematological toxicities (except lymphopenia) | 1st occurrence:<br><br>Hold until ≤ Grade 1 or baseline; resume at same dose.<br><br>2nd and subsequent occurrence(s):<br><br>Hold until ≤ Grade 1 or baseline; resume at a reduced dose (see table above). A larger dose reduction may be selected at the | Hold; resume at same dose. |

| | | |
|---|---|---|
| | discretion of the physician. | |
| • Any pulmonary toxicity<br>• Severe mucocutaneous toxicity<br>• Serious/life-threatening cardio-pulmonary events<br>• Reactivation of tuberculosis or hepatitis B; evidence of active hepatitis<br>• PML / RPLS | Discontinue. | |
| *For dose reductions to < 100 mg for > 2 weeks, consider discontinuing. Patients who discontinue venetoclax should discontinue rituximab treatment, if applicable.<br><br>**Missed or delayed doses may be administered at a later time point, based on physician's discretion.<br><br>***G-CSF may be administered with venetoclax if clinically indicated. | | |

Management of Rituximab (IV) Infusion-Related Reactions:

Also refer to the CCO guideline for detailed description of Management of Cancer Medication-Related Infusion Reactions.

| Grade | Management | Re-challenge |
|---|---|---|
| 1 or 2 | • Stop or slow the infusion.<br>• Manage the symptoms.<br>• Restart:<br>  ○ Once symptoms have resolved, restart IV at 50% of the rate at which the IR occurred | • Re-challenge IV at 50% of the administration rate at which the IR occurred and with pre-medications.<br>• Consider adding oral montelukast ± oral acetylsalicylic acid |
| 3 or 4 | • Stop the infusion.<br>• Aggressively manage symptoms. | • Consider clinical benefit and risks of further treatment. Consider patient factors, severity and nature of the IR and availability of suitable alternative |

| | | |
|---|---|---|
| | | treatment.<br>• Consider desensitization for patients with recurrent reactions despite pre-medications and a slower infusion rate. |

**Hepatic Impairment**

Monitor closely for toxicity at initiation and during ramp-up phase.

| Bilirubin | | AST | Venetoclax Dose | Rituximab (IV or subcut) dose |
|---|---|---|---|---|
| ≤ ULN | and | > ULN | No dose adjustment | No dosage adjustment required; stop if evidence of hepatitis. |
| >1 - 3 x ULN | and | Any | | |
| >3 x ULN | and | Any | 50% reduction | |

**Renal Impairment**

Patients with reduced renal function (CrCl < 80 mL/min) have an increased risk of TLS and may require more intensive TLS prophylaxis and monitoring.

| Creatinine Clearance (mL/min) | Venetoclax Dose | Rituximab (IV or subcut) Dose |
|---|---|---|
| ≥ 30 | No dose adjustment | No dosage adjustment |
| < 30 | Limited data | |

**Dosage in the Elderly**

No dose adjustment required for venetoclax and rituximab (IV or subcut). Exercise caution as older patients receiving rituximab (IV or subcut) are more likely to experience serious adverse events (including cardiac, pulmonary, or other grade 3/4 toxicity). Patients ≥ 65 years of age experienced higher incidences of diarrhea, peripheral edema, dizziness, increased serum creatinine, constipation, fever, and fall than younger patients.

**Dosage based on ethnicity**

Asian patients had 67% higher exposure than non-Asian patients with venetoclax; however, no dose

adjustment is necessary.

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## F - Adverse Effects

Refer to venetoclax, riTUXimab, riTUXimab (subcut) drug monograph(s) for additional details of adverse effects.

| Very common (≥ 50%) | Common (25-49%) | Less common (10-24%) | Uncommon (< 10%),<br><br>but may be severe or life-threatening |
|---|---|---|---|
| • Infusion and hypersensitivity reactions (with rituximab IV; may be severe)<br>• Myelosuppression (mostly neutropenia) +/- infection (including atypical, viral reactivation), bleeding (may be severe) | • Diarrhea<br>• Administration-related reactions, including cutaneous (with rituximab subcut) | • Edema<br>• Nausea, vomiting<br>• Abdominal pain<br>• Muskuloskeletal pain<br>• Headache<br>• Secondary malignancy<br>• Rash, pruritius (may be severe)<br>• Fatigue<br>• Cough, Dyspnea<br>• Abnormal electrolytes<br>• Paresthesia<br>• Dizziness<br>• Constipation<br>• Mucositis<br>• Hypotension<br>• Flu-like symptoms | • Hemolytic anemia<br>• Multiple organ dysfunction syndrome<br>• Arrhythmia, cardiotoxicity<br>• Arterial/venous thromboembolism<br>• Bowel obstruction/perforation<br>• Pneumonitis<br>• RPLS / PRES, PML<br>• Optic and cranial nerve disorder<br>• Tumour lysis syndrome<br>• Nephrotoxicity<br>• Vasculitis<br>• Hemolysis<br>• Hyperviscosity |

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## G - Interactions

Refer to venetoclax, riTUXimab, riTUXimab (subcut) drug monograph(s) for additional details.

Formal drug interaction studies have not been performed with rituximab (subcut).

- Strong CYP3A4 inhibitors are **contraindicated during venetoclax intiation and ramp-up phase**. Avoid concomitant use at steady state. If concomitant use is required, reduce venetoclax dose to 100 mg or less; resume previous venetoclax dose 2 to 3 days after stopping the inhibitor.
- Avoid concomitant use of venetoclax with moderate CYP3A4 inhibitors; reduce venetoclax dose by at least 50% if concomitant use is unavoidable. Resume previous venetoclax dose 2 to 3 days after stopping the inhibitor.
- When used concomitantly with P-gp inhibitors, reduce the venetoclax dose by at least 50%; resume previous venetoclax dose 2 to 3 days after stopping the inhibitor. Venetoclax dose adjustment is not required when co-administered with azithromycin.
- Avoid concomitant use of venetoclax with both strong and moderate CYP3A4 inducers; consider alternative treatments.
- Avoid P-gp and BCRP substrates with a narrow therapeutic index (i.e. digoxin); if must be used, administer at least 6 hours before venetoclax.
- Warfarin concentrations may be increased; monitor INR closely if used together with venetoclax.
- Consider withholding antihypertensive agents temporarily 12 hours prior to and during rituximab administration.

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## H - Drug Administration and Special Precautions

Refer to venetoclax, riTUXimab, riTUXimab (subcut) drug monograph(s) for additional details.

### Administration: Venetoclax

**Note:** Venetoclax is only available through pharmacies that are part of AbbVie's managed distribution program.

- Administer venetoclax with a meal and water at approximately the same time each day.
- Tablets should be swallowed whole and not be chewed, crushed, or broken prior to swallowing.
- Manufacturer recommends administering venetoclax at least 30 minutes prior to starting the rituximab infusion.
- If a dose is missed, it should be taken as soon as possible (within 8 hours of the time it is

normally taken). If > 8 hours, the dose should be skipped and the usual dosing schedule resumed the following day.
- If the patient vomits after taking a dose, no additional dose should be taken. The next dose should be taken at the usual time.
- Grapefruit products, Seville oranges, and starfruit must not be used during the ramp up period and should be avoided during treatment.
- Store between 2 and 30$^{o}$C.

**Administration: Rituximab**

**Note:** Different rituximab products are **not interchangeable.**

**Rituximab IV and Subcutaneous formulations are not interchangeable.** The dosing and concentrations of these products are different.

Rituximab should be administered in a setting where full resuscitation facilities are immediately available, and under the close supervision of someone experienced and capable of dealing with severe infusion-related reactions.

**Administration: Rituximab (IV)**

- DO NOT administer as an IV push or bolus.
- Dilute to a final concentration of 1-4 mg/mL in normal saline or D5W.
- To avoid foaming, gently invert the bag to mix the solution.
- Do not admix with other drugs.
- Administer rituximab through a dedicated line.
- Compatible with PVC or polyethylene bags.
- Keep vials refrigerated; do not freeze. Protect from light.
- **Infusion rates:**
  - First infusion:
    - Recommended to be administered over a graduated rate: initial rate of 50 mg/h, then escalate rate in 50 mg/h increments every 30 minutes, to a maximum of 400 mg/h (about 4.25 hours in total).
  - Subsequent infusions:
    - If no severe infusion reaction (grade 3 or 4) occurred with the first cycle, a rapid infusion of IV rituximab over a total of 90 minutes can be initiated with cycle 2 (20% of the dose in the first 30 min then the remaining 80% over 60 min).
    - OR initial rate of 100 mg/h, then escalate rate in 100 mg/h increments every 30 minutes, to a maximum of 400 mg/h as tolerated (about 3.25 hours in total).
    - Alternatively, subcutaneous administration of rituximab can be considered starting with cycle 2.
- When bulky disease present or WBC > 25-50 x $10^{9}$/L, consider:
  - A slower infusion rate, or
  - Split dosing over days 1-2, or
  - Delaying rituximab treatment until chemotherapy has reduced the lymphocyte count

**Administration: Rituximab (subcut)**

Refer to Safety Considerations for the Implementation of Subcutaneous Rituximab Formulation

- Rituximab (subcut) must not be self-administered.
- Rituximab (subcut) is given subcutaneously into the abdominal wall only. Do not give in areas where the skin is red, tender, hard, bruised, or where there are moles or scars.
- Give subcutaneously approximately over 7 minutes.
- Observe for at least 15 minutes after administration.
- Cold compresses and topical steroids may be helpful for local cutaneous reactions.
- Compatible with polypropylene or polycarbonate syringes.
- Keep vials refrigerated in the outer carton; do not freeze. Protect from light.

Also refer to the CCO guideline for detailed description of Management of Cancer Medication-Related Infusion Reactions.

**Contraindications:**

- Patients who have a hypersensitivity to any of the drugs or any of their components, or known hypersensitivity and anaphylactic reactions to proteins of similar mouse or human origin, or to Chinese Hamster Ovary (CHO) cell protein.
- Concomitant use of strong CYP3A inhibitors with venetoclax at initiation and during ramp-up phase.
- Rituximab (IV or subcut) is contraindicated in patients who have or have had PML, have active and/or severe infections, active hepatitis B, or severely immunocompromised (e.g. AIDS patients with very low CD4 or CD8 counts).

**Warnings/Precautions:**

- Tumour lysis syndrome (see Premedication and Supportive Measures section for prophylaxis).
- Safety and efficacy of live attenuated vaccines during or after treatment have not been studied. Live vaccines should not be administered during treatment and thereafter until B-cell recovery. Patients should be advised that vaccinations may be less effective. Patients should be advised that vaccinations may be less effective with this treatment.
- Exercise caution in patients with a history of recurring or chronic infections or with underlying conditions which may further predispose patients to serious infection. Patients may have increased risk of infection following rituximab treatment.
- Prior to starting rituximab in HBV seropositive patients, consultation with a liver disease expert is recommended to determine ongoing monitoring of HBV reactivation and its management.
- Exercise caution in patients with neutrophil counts < 1.5 x $10^9$/L and/or platelets < 75 x $10^9$/L due to limited experience of rituximab in this patient group .
- Use rituximab with *extreme caution* in patients with pre-existing cardiovascular disease or in patients with high tumour burden. Consider steroids ± slow infusions or infusions split over 2 days for patients with bulky disease or > 25 x $10^9$/L circulating malignant cells.
- Use rituximab with caution in patients with pulmonary insufficiency or lung tumour infiltration, and in patients with myelosuppression.

**Pregnancy and Lactation:**

- This regimen is not recommended for use in pregnancy. Adequate contraception should be used by patients and their partners while on treatment and after the last treatment dose. Recommended methods and duration of contraception may differ depending on the treatment. Refer to the drug monograph(s) for more information.
- Breastfeeding is not recommended during this treatment and after the last treatment dose. Refer to the drug monograph(s) for recommendations after the last treatment dose (if available).
- Fertility effects:
  - Venetoclax: Likely
  - Rituximab: Unknown

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## I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Refer to the hepatitis B virus screening and management guideline for monitoring during and after treatment.

Recommended Clinical Monitoring

- Tumour burden assessment; Prior to starting treatment
- CBC; Baseline, before each cycle, and as clinically indicated
- Liver function tests; Baseline, before each cycle, and as clinically indicated
- Blood chemistry and electrolytes (for TLS - including potassium, uric acid, phosphorous, calcium, creatinine); Before starting venetoclax, at 6 to 8 hours post-dose, and 24 hours post-dose for the first dose of venetoclax 20 mg and 50 mg, and pre-dose at subsequent ramp-up doses, at each visit, and as clinically indicated. Also refer to Prophylaxis for TLS section.
- Hypersensitivity reactions; During and for at least 15 minutes after each rituximab dose (longer in patients at higher risk of hypersensitivity reactions)
- INR; Baseline and at each visit, or as clinically indicated (for patients taking warfarin)
- Secondary malignancies (including non-melanoma skin and non-skin); At each visit
- Clinical toxicity assessment of infusion/hypersensitivity reactions, fever, infection, edema, bleeding, fatigue, musculoskeletal pain, rash, headache, GI, pulmonary,

CNS, and cardiovascular effects; At each visit

- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

Suggested Clinical Monitoring

- Cardiovascular symptoms (in patients who have cardiac conditions or recurrent cardiac events with rituximab); At each visit

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## J - Administrative Information

| | |
|---|---|
| Approximate Patient Visit | Cycle 1: 5 hours; Cycles 2-6: 3-5 hours (IV), 0.75 hour (Subcut) |
| Pharmacy Workload (average time per visit) | 20.946 minutes |
| Nursing Workload (average time per visit) | 69.167 minutes |

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## K - References

Rituximab drug monograph. Ontario Health (Cancer Care Ontario).

Rituximab (subcut) drug monograph. Ontario Health (Cancer Care Ontario).

Seymour JF, Kipps TJ, Eichhorst B, et al. Venetoclax-rituximab in relapsed or refractory chronic lymphocytic leukemia. N Engl J Med. 2018;378:1107-20.

Venetoclax drug monograph. Ontario Health (Cancer Care Ontario).

**November 2023** Modified Pregnancy/breastfeeding section

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## M - Disclaimer

***Regimen Abstracts***

*A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.*

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***Regimen Monographs***

*Refer to the New Drug Funding Program or Ontario Public Drug Programs websites for the most up-to-date public funding information.*

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