

BC Cancer Protocol Summary for Treatment of Locally Advanced Cervical Cancer with Pembrolizumab, CISplatin and Radiation Therapy

Protocol Code: GOCXPEMCRT

Tumour Group: Gynecology

Contact Physician: GO Systemic Therapy

ELIGIBILITY:

Patient must have:

- Newly diagnosed histologically confirmed squamous carcinoma, adenocarcinoma, or adenosquamous carcinoma of cervix, meeting one of the staging criteria below:
 - Any T stage if pelvic and/or para-aortic lymph node positive
 - T3 or T4 irrespective of nodal status

Patient should have:

- Good performance status
- Adequate hematologic, hepatic and renal function
- Access to a treatment center with expertise to manage immune-mediated adverse reactions of pembrolizumab

Note:

- Patients who started treatment with GOCXCRT between 1 February 2026 and 1 March 2026, may switch to GOCXPEMCRT

EXCLUSIONS:

Patient must not have:

- Neuroendocrine or small cell carcinoma
- Evidence of distant metastases
- Contraindication to CISplatin (e.g. deafness, intolerance to fluid load, neuropathy)

CAUTIONS:

- Active, known or suspected autoimmune disease
- Patients with long term immunosuppressive therapy or systemic corticosteroids (requiring more than 10 mg predniSONE/day or equivalent)

TESTS:

- Baseline: CBC & Diff, creatinine, ALT, alkaline phosphatase, total bilirubin, sodium, potassium, TSH, random glucose, morning serum cortisol, chest x-ray or CT chest if not previously done
- Baseline, if clinically indicated: magnesium, calcium, CA 19-9, CA125, CA 15-3, CEA, SCC, BNP, troponin, creatine kinase, serum or urine HCG (required for women of childbearing potential if pregnancy suspected), ECG, echocardiogram
- Prior to Day 1 of each cycle: CBC & Diff, creatinine, ALT, alkaline phosphatase, total bilirubin, sodium, potassium, TSH
- Cycle 1 and 2, prior to Days 8 and 15: CBC & Diff, creatinine. Cycle 2 Day 15 bloodwork only required if optional CISplatin is ordered.
- If clinically indicated: sodium, potassium, magnesium, calcium, GGT, morning serum cortisol, lipase, random glucose, serum or urine HCG (required for women of childbearing potential if pregnancy suspected), free T3 and free T4, serum ACTH levels, testosterone, estradiol, FSH, LH, CA 19-9, CA125, CA 15-3, CEA, SCC, creatine kinase, troponin, ECG, chest x-ray
- Weekly telephone nursing assessment for signs and symptoms of side effects while on treatment (optional).

OPTIONAL PREHYDRATION:

- D5W-1/2NS 1000 mL with potassium chloride 20 mEq and magnesium sulfate 2 g IV over 2 hours, before CISplatin.

PREMEDICATIONS:

- For Cycles 1 and 2: Antiemetic protocol for highly emetogenic chemotherapy (see protocol [SCNAUSEA](#)).
- For Cycles 3 to 20: Antiemetics are not usually required. If required, antiemetic protocol for low emetogenicity (see [SCNAUSEA](#)).
- If prior infusion reactions to pembrolizumab: diphenhydramine 50 mg PO, acetaminophen 325 to 975 mg PO, and hydrocortisone 25 mg IV 30 minutes prior to treatment

TREATMENT:

Note: Cycles 1 and 2 are given concurrently with radiation therapy. Radiation should be targeted to start shortly after CISplatin infusion is completed. If radiation therapy is cancelled, do not give CISplatin that day; postpone until radiation therapy resumes. Pembrolizumab should be continued during CISplatin or radiation therapy delay.

Cycle 1: starts on first day of radiation therapy

Drug	Dose	BC Cancer Administration Guidelines
pembrolizumab	2 mg/kg* on Day 1 (maximum 200 mg)	IV in 50 mL NS over 30 minutes using a 0.2 micron in-line filter
CISplatin	40 mg/m ² on Day 1, 8 and 15	IV in NS 500 mL with mannitol 30 g and magnesium sulfate 2 g, over 60 minutes

Cycle 2: to start 21 days after Cycle 1 Day 1

Drug	Dose	BC Cancer Administration Guidelines
pembrolizumab	2 mg/kg* on Day 1 (maximum 200 mg)	IV in 50 mL NS over 30 minutes using a 0.2 micron in-line filter
CISplatin	40 mg/m ² on Day 1, 8 and optional Day 15	IV in NS 500 mL with mannitol 30 g and magnesium sulfate 2 g, over 60 minutes

Cycle 3 to 5: to start 21 days after Cycle 2 Day 1

Drug	Dose	BC Cancer Administration Guidelines
pembrolizumab	2 mg/kg* (maximum 200 mg)	IV in 50 mL NS over 30 minutes using a 0.2 micron in-line filter

- Repeat every 21 days for 3 cycles (i.e. Cycles 3 to 5)

Cycles 6 to 20: Cycle 6 starts 21 days after Cycle 5

Drug	Dose	BC Cancer Administration Guidelines
pembrolizumab	4 mg/kg* (maximum 400 mg)	IV in 50 mL NS over 30 minutes using a 0.2 micron in-line filter

- Repeat every 42 days for 15 cycles (i.e. Cycles 6 to 20). Patients may have treatment breaks for reasons other than progression (e.g., toxicities, treatment holiday, vacation).

*Select dose per Dose Banding Table (appendix).

DOSE MODIFICATIONS :

- For pembrolizumab:** no specific dose modification. Toxicity managed by treatment delay and other measures (see [SCIMMUNE](#) protocol for management of immune-mediated adverse reactions to checkpoint inhibitors immunotherapy)

2. Hematological: for CISplatin

ANC (x 10 ⁹ /L)	Management
Greater than or equal to 0.8	Proceed with CISplatin
Less than 0.8	Consider dose reduction or delay

Platelets (x 10 ⁹ /L)	Management
Greater than or equal to 80	Proceed with treatment
Less than 80	Hold CISplatin

3. Renal dysfunction: for CISplatin

Creatinine Clearance (mL/minute)	Management
Greater than or equal to 50	Proceed with treatment
Less than 50	Delay CISplatin, recheck in 1 week
Less than 50 after overnight hydration	Discontinue CISplatin

PRECAUTIONS:

- Renal Toxicity:** Nephrotoxicity is common with CISplatin. Encourage oral hydration. Avoid nephrotoxic drugs such as aminoglycosides.
- Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively. Refer to BC Cancer [Febrile Neutropenia Guidelines](#).
- Serious immune-mediated reactions to pembrolizumab:** these can be severe to fatal and usually occur during the treatment course. They may include enterocolitis, intestinal perforation or hemorrhage, hepatitis, dermatitis, neuropathy, endocrinopathy, as well as toxicities in other organ systems. Early diagnosis and appropriate management are essential to minimize life-threatening complications (see [SCIMMUNE](#) protocol for management of immune-mediated adverse reactions to checkpoint inhibitors immunotherapy).
- Infusion-related reactions:** isolated cases of severe reaction have been reported. In case of a severe reaction, pembrolizumab infusion should be discontinued and appropriate medical therapy administered. Patients with mild or moderate infusion reaction may receive pembrolizumab with close monitoring. Premedications with acetaminophen and antihistamine may be considered if there is a history of reaction. See [SCDRUGRX](#) protocol for management of infusion-related reactions to systemic therapy agents.

Contact the GO Systemic Therapy physician at your regional cancer centre or GO Systemic Therapy Chair with any problems or questions regarding this treatment program.

REFERENCES:

- Pembrolizumab (Keytruda) Canada's Drug Agency (CDA-AMC) Reimbursement Recommendation. Canadian Journal of Health Technologies. October 2025; 5(10); 1-24.
- Lorusso D, Xiang Y, Hasegawa K, et al. Pembrolizumab or Placebo with Chemoradiotherapy Followed by Pembrolizumab or Placebo for Newly Diagnosed, High-risk, Locally Advanced Cervical Cancer (ENGOT-cx11/ GOG-3047/KEYNOTE-A18): a Randomised, Double-blind, Phase 3 Clinical Trial. Lancet 2024; 403: 1341–50.
- Lorusso D, Xiang Y, Hasegawa K, et al. Pembrolizumab or Placebo with Chemoradiotherapy Followed by Pembrolizumab or Placebo for Newly Diagnosed, High-risk, Locally Advanced Cervical Cancer (ENGOT-cx11/ GOG-3047/KEYNOTE-A18): Overall Survival Results from a Randomised, Double-blind, Placebo-controlled, Phase 3 Trial. Lancet 2024; 404: 1321–32.

Appendix. Dose Bands

PEMBROLIZUMAB DOSE BANDING TABLE (2 mg/kg capped 200 mg)

Ordered Dose (mg)		Rounded dose (mg)
From:	To:	
Less than 70		Pharmacy prepares specific dose
70	80.49	75
80.5	92.49	85
92.5	110.49	100
110.5	137.49	125
137.5	162.49	150
162.5	187.49	175
187.5	200	200

PEMBROLIZUMAB DOSE BANDING TABLE (4 mg/kg capped 400 mg)

Ordered Dose (mg)		Rounded dose (mg)
From:	To:	
Less than 137.5		Pharmacy prepares specific dose
137.5	162.49	150
162.5	187.49	175
187.5	221.49	200
221.5	242.49	225
242.5	264.49	250
264.5	284.49	275
284.5	332.49	300
332.5	374.49	350
374.5	400	400