Regimen Monograph

A - Regimen Name

XELOX+BEVA Regimen

Capecitabine (Xeloda®)-Oxaliplatin-Bevacizumab

Disease Site

Gastrointestinal
- Colorectal
- Small bowel and appendix

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

Treatment of metastatic colorectal, small bowel or appendiceal cancer

Supplementary Public Funding

capecitabine
ODB - General Benefit (capecitabine)

bevacizumab
New Drug Funding Program (Bevacizumab (Biosimilar) - Metastatic Colorectal, Small Bowel, or Appendiceal Cancer) (NDFP Website)

back to top

B - Drug Regimen

Different bevacizumab products are **not interchangeable**.

bevacizumab	7.5 mg /kg	IV	Day 1
oxaliplatin	130 mg /m²	IV	Day 1
capecitabine	1000 mg /m²	PO	BID, Days 1 to 14

Note: a dose of capecitabine 750 mg/m^2 PO BID was used in a small phase 2 study in small bowel cancer (Overman MJ et al.)

back to top

C - Cycle Frequency

REPEAT EVERY 21 DAYS

Until disease progression or unacceptable toxicity

back to top

D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate
No routine prophylaxis for capecitabine

Also refer to CCO Antiemetic Recommendations.

Screen for hepatitis B virus in all cancer patients starting systemic treatment. Refer to the hepatitis B virus screening and management guideline.

Oxaliplatin premedication (prophylaxis for infusion reactions):

- There is insufficient evidence that routine prophylaxis with pre-medications reduces IR rates.
- Consider corticosteroids and H1-receptor antagonists ± H2-receptor antagonists in high-risk patients (i.e. ≥ cycle 6, younger age, female gender, prior platinum exposure, platinum-free interval ≥ 3 years).

Bevacizumab premedication (prophylaxis for infusion reactions):

- Routine primary prophylaxis is not recommended; the use of secondary prophylaxis pre-medications should be based on clinical judgement.

Other Supportive Care:

- Topical emollients (e.g. hand creams, udder balm) therapy may ameliorate the manifestations of hand-foot syndrome in patients receiving capecitabine.
- Standard antidiarrheal agents (e.g. loperamide) should be initiated, as medically appropriate, as early as possible.
- Patients should be counselled about cold avoidance prior to receiving oxaliplatin, since cold temperatures can precipitate or exacerbate acute neurological symptoms.

back to top

E - Dose Modifications

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

Patients should be tested for DPD deficiency before starting treatment with capecitabine. Refer to the DPD Deficiency Guidance for Clinicians for more information.

In patients with unrecognized DPD deficiency, acute, life-threatening toxicity may occur; if acute grade 2-4 toxicity develops, treatment should be stopped immediately and permanent discontinuation considered based on clinical assessment of the toxicities.

Bevacizumab should not be initiated in patients with recurrent hemoptysis, uncontrolled hypertension or wounds that require healing.

Prior to treatment, a dental evaluation should be performed and major dental procedures completed.

Dosage with toxicity

Do not retreat until neutrophils ≥ 1.5 x 10^9 /L, platelet counts ≥ 100 x 10^9 /L and major organ toxicity has resolved to ≤ grade 1.

Oxaliplatin

Neurotoxicity was graded based on the following scales in some metastatic colorectal cancer trials.

Neurotoxicity Grade	Description
1	Resolved and did not interfere with functioning
2	Interfered with function but not daily activities
3	Pain or functional impairment that interfered with daily activities
4	Persistent impairment that is disabling or life-threatening

Dose Modifications

Toxicity Grade	Oxaliplatin Dose^
Persistent[1] Grade 2 neurotoxicity	↓ 25%
Transient[1] Grade 3 neurotoxicity	↓ 25%
Persistent[1] Grade 3 neurotoxicity or any Grade 4 neurotoxicity	Discontinue
≥ Grade 3 GI toxicity (after prophylaxis) OR ≥ Grade 3 Platelets OR ≥ Grade 3 Neutropenia (including febrile neutropenia)	↓ 25%
Sepsis / septic shock	Discontinue
Other ≥ grade 3 related organ toxicity [2]	Consider ↓ 25%
Pharyngolaryngeal dysesthesia	Hold; then increase duration of infusion to 6 hours[3]
Pneumonitis	Hold, investigate; discontinue permanently if confirmed.
Anaphylactic-like reaction	Discontinue permanently
RPLS /PRES	
Hemolytic uremic syndrome or any signs of microangiopathic hemolytic anemia	
Disseminated intravascular coagulation (DIC)	
QT prolongation	
Intestinal ischemia or duodenal ulcer	
Symptoms of rhabdomyolysis	

^Do not re-treat until the ANC ≥ 1.5 x 10^9/L and the platelets ≥ 100 x 10^9/L, GI and neurotoxicities have resolved and other non-hematologic toxicities ≤ grade 1

[1] Transient = >7days - <1 cycle; persistent = ≥ 1 cycle

[2] For skin toxicity, reduce capecitabine dose only

[3] If oxygen saturation is normal, an anxiolytic agent may be given.

Capecitabine

Mandatory for gastrointestinal, dermatological toxicity and hyperbilirubinemia. Practitioner may elect not to reduce dose for other toxicities unlikely to become serious or life-threatening.

Missed or omitted doses of capecitabine should not be replaced. Doses should not be re-escalated if reduced for toxicity.

Toxicity	Action During a Course of Therapy	Dose Adjustment for Next Cycle (% of starting dose)
Grade 1	Maintain dose level	Maintain dose level
Grade 2 1st appearance 2nd appearance 3rd appearance 4th appearance	 Hold until resolved to ≤ grade 1 Hold until resolved to ≤ grade 1 Hold until resolved to ≤ grade 1 Discontinue treatment permanently	 100% 75% 50% Not applicable
Grade 3 1st appearance 2nd appearance 3rd appearance OR any evidence of Stevens-Johnson syndrome (i.e. sloughing)	 Hold until resolved to ≤ grade 1 Hold until resolved to ≤ grade 1 Discontinue treatment permanently	 75% 50% Not applicable
Grade 4 1st appearance 2nd appearance	 Discontinue permanently or If physician deems it to be in the patient's best interest to continue and no evidence of Stevens-Johnson syndrome or toxic epidermal necrolysis, interrupt until resolved to ≤ grade 1. Discontinue permanently	 Discontinue or 50% Not applicable

Bevacizumab:

Dose reductions are not recommended. Bevacizumab should be held or discontinued based on toxicity.

Bevacizumab action	**Toxicity**		
	Any grade	**Grade 3**	**Grade 4**
Hold:	Uncontrolled hypertension		
	Delayed wound healing		
	Proteinuria ≥ 2g/ 24 hours*		
	Surgery**		
Discontinue:		Hypertension not controlled with medical management	Hypertension
	Wound dehiscence, poor healing requiring medical intervention; necrotizing fasciitis		
	Nephrotic syndrome; non-recovery of proteinuria ≥ 2g/24 hours		
	Tracheo-esophageal fistula, other non-GI fistulae		Any internal fistula
	GI Perforation or fistula		
	PRES, hypertensive encephalopathy		
	Arterial thromboembolism	Pulmonary embolism	Venous thromboembolism (including pulmonary embolism)
	Symptomatic cardiac failure		
	Recurrent hemoptysis > 2.5 mL	Bleeding (any)	Bleeding (any)
	Intracranial bleeding		
* may restart when < 2g/24hrs ** for 28 days PRIOR (if surgery elective) and AFTER major surgery, or until wound healed			

Management of Infusion-related reactions:

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

Oxaliplatin:

Grade	Management	Oxaliplatin Re-challenge
1 or 2	• Stop or slow the infusion rate. • Manage the symptoms. Restart: • After symptom resolution, restart with pre-medications ± reduced infusion rate.	• Consider pre-medications* and infusing at a reduced infusion rate prior to re-challenge. • May consider adding oral montelukast ± oral acetylsalicylic acid.
3 or 4	• Stop treatment. • Aggressively manage symptoms.	• Re-challenge is discouraged, especially if vital symptoms have been affected. • Consider desensitization if therapy is necessary.

* Up to 50% of patients can experience recurrent reactions during re-challenge **despite** using pre-medications (e.g. corticosteroid and H1/H2-receptor antagonist).

Bevacizumab:

Grade	Management	Bevacizumab Re-challenge
1 or 2	• Stop or slow the infusion rate. • Manage the symptoms. **Restart:** • Once symptoms resolve, the infusion can be restarted at a slower rate, unless a serious reaction occurred.	• No specific recommendations can be made at this time

3 or 4	• Stop treatment. • Aggressively manage symptoms.	

Hepatic Impairment

Hepatic impairment	Oxaliplatin (% previous dose)	Capecitabine (% previous dose)*	Bevacizumab
Mild	No dose adjustment required	No starting dose adjustment necessary	No data. Not a major route of metabolism or excretion.
Moderate			
Severe	No data available	No data available	

*use capecitabine dose modification table above for hepatotoxicity during treatment

Renal Impairment

Creatinine Clearance (mL/min)	oxaliplatin (% previous dose)	capecitabine (% previous dose)	bevacizumab
≥50	No change	100%, with close monitoring	No data. Not a major route of metabolism or excretion.
30 to <50	Caution	75 % (use with caution)	
<30	Discontinue	CONTRAINDICATED	

Dosage in the Elderly

For oxaliplatin, patients ≥ 65 years had a higher incidence of GI toxicity, myelosuppression, syncope and fatigue. No dose adjustments were needed but caution should be exercised.

For capecitabine, older patients are more susceptible to the effects of fluoropyrimidine-based therapies with increased grade 3 / 4 adverse effects, especially when used in combination. Starting dosage adjustment is not recommended, but dose modifications should be performed for toxicity (see tables above).

Use bevacizumab with caution; patients > 65 years old have an increased risk of arterial thrombotic events as well as myelosuppression, fatigue, proteinuria, hypertension, dizziness, dysphonia, anorexia and GI effects (except gastrointestinal perforation).

Dosage based on gender

Females were observed to have higher number of severe adverse effects with oxaliplatin than males.

back to top

F - Adverse Effects

Refer to oxaliplatin, capecitabine, bevacizumab drug monograph(s) for additional details of adverse effects

Very common (≥ 50%)	Common (25-49%)	Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
• Sensory neuropathy (may be severe) • Myelosuppression +/- infection, bleeding (may be severe) • Nausea, vomiting • Hand-foot syndrome • Increased LFTs (may be severe) • Diarrhea (may be severe)	• Fatigue • Hypertension (may be severe) • Mucositis • Pharyngolaryngeal dysesthesia (with oxaliplatin) • Proteinuria (may be severe) • Alopecia (generally mild)	• Constipation • ↑ Bilirubin • Venous thromboembolism • Edema • Rash (may be severe) • Hyperglycemia • Musculoskeletal pain • Insomnia • Cough, dyspnea • Anorexia • Weight changes • Cardiotoxicity • Dysgeusia • Injection site reactions • Abnormal electrolytes • Hypersensitivity • Dysphonia	• Arterial thromboembolism • QT interval prolonged • Pulmonary hypertension • GI obstruction, perforation • Fistulas • Necrotizing fasciitis • Osteonecrosis (jaw, other) • Delayed wound healing • Hemorrhage (severe) • INR/ prothrombin time increased • Disseminated intravascular coagulation • Thrombotic microangiopathy • Hemolytic uremic syndrome • Hemolysis • Idiopathic

			thrombocytopenic purpura • Hepatic failure • Nephrotoxicity • Pancreatitis • Pneumonitis • Rhabdomyolysis • PRES/RPLS • Leukoencephalopathy • Veno-occlusive disease • Guillain-Barre syndrome • Eye disorders

back to top

G - Interactions

Refer to oxaliplatin, capecitabine, bevacizumab drug monograph(s) for additional details

- Concomitant use with sorivudine or analogues is **contraindicated**, given the increased risk of capecitabine toxicity (may be fatal). Wait at least 4 weeks after sorivudine (or chemically related analogues) treatment before starting capecitabine.
- Avoid concomitant administration with phenytoin; capecitabine may increase levels. Monitor phenytoin levels if must be given together.
- Do not use with diuretics in patients who are receiving bevacizumab and platinum-based chemotherapy (oxaliplatin).
- Monitor PT/INR when this treatment is administered with warfarin or other anticoagulants; adjust anticoagulant dose accordingly.
- Caution with the use of proton pump inhibitors and monitor for reduced effectiveness of capecitabine; consider switching to a magnesium and aluminum hydroxide-containing antacid.
- Caution and monitor with the coadministration of leucovorin as this may increase capecitabine toxicity.
- Monitor for toxicity when using oxaliplatin with other nephrotoxic drugs, QT-prolonging drugs or drugs associated with rhabdomyolysis.

back to top

H - Drug Administration and Special Precautions

Refer to oxaliplatin, capecitabine, bevacizumab drug monograph(s) for additional details

Administration:

Bevacizumab

Different bevacizumab products are **not interchangeable**.

- **Do not** administer as an IV push or bolus.
- Bevacizumab infusions should **not** be administered or mixed with dextrose or glucose solutions due to potential for drug degradation.
- Mix in 100 mL bag NS. (Final concentration should be 1.4 -16.5 mg/mL).
- Compatible with PVC or polyolefin bags.
- Do not shake. Should not be mixed or diluted with other drugs.
- Infuse over 90 minutes as loading dose, if tolerated next infusion can be given over 60 minutes; can thereafter be given over 30 minutes as maintenance dose
- Bevacizumab rapid infusion (over 10 minutes) has safely been administered with no significant increase in infusion reactions (for 5mg/kg and 7.5mg/kg doses).
- Refrigerate unopened vials and protect from light; do not freeze.

Oxaliplatin

- Oxaliplatin is administered by intravenous infusion.
- May be mixed in 250-500 mL bag (D5W only). **Do not** mix with NS, chloride containing or alkaline solutions.
- Administer by slow infusion. Concentration must be between 0.2 to 0.7 mg/mL
- Infuse IV over 2 hours. Increasing infusion time to 6 hours may decrease acute toxicity such as pharyngolaryngeal dysesthesia.
- Do not mix oxaliplatin with other drugs in the same infusion bag or infusion line.
- If another drug is given before oxaliplatin, flush infusion line with D5W before giving oxaliplatin. Flush the line with D5W after oxaliplatin before giving a subsequent drug.

- The compatibility of oxaliplatin solution for infusion has been tested with representative, PVC-based, administration sets.
- Do not use with injection equipment containing aluminum, as this can degrade platinum compounds.
- Unopened vials should be stored at 15-30°C; protect from light.

Capecitabine

- Oral self-administration; drug available by outpatient prescription.
- Doses are given orally approximately 12 hours apart, within 30 minutes after the end of a meal.
- Swallow tablets whole; do not crush or cut tablets.
- If a capecitabine dose is missed, skip this and give the next dose at the usual time. Missed or omitted doses should not be replaced.
- Store tablets at 15ºC to 30ºC in the original package.

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

Contraindications:

- Patients who have a known hypersensitivity to capecitabine, 5-fluorouracil, oxaliplatin or other platinum agents (e.g. cisplatin), bevacizumab, or any ingredient in the formulation or component of the container.
- Patients with known hypersensitivity to Chinese hamster ovary cell product or to other recombinant human or humanized antibodies
- Patients who are pregnant or breastfeeding
- Patients with severe renal impairment (CrCl <30 mL/min)
- Patients with untreated CNS metastases
- Patients with known near or complete absence of DPD (dihydropyrimidine dehydrogenase) deficiency. Refer to the DPD Deficiency Guidance for Clinicians for more information.
- Concomitant use with sorivudine or related analogues (i.e. brivudine), given potential fatal drug interaction

Warnings/Precautions:

- Patients be counselled about cold avoidance prior to receiving oxaliplatin, since cold temperatures can precipitate or exacerbate acute neurological symptoms.
- Oxaliplatin may cause dizziness or visual disturbances in some patients (including transient vision loss); patients should exercise caution when driving or operating machinery.
- Use capecitabine with extreme caution in patients with partial DPD deficiency. Refer to the DPD Deficiency Guidance for Clinicians for more information.
- Use capecitabine with caution in patients with risk factors for dehydration, pre-existing renal dysfunction or on nephrotoxic agents.
- Use capecitabine with caution in patients taking anticoagulants such as warfarin (see Interactions section)
- Use caution in patients with a history of cardiovascular disease, cardiac failure or arterial thromboembolism.
- Bevacizumab should not be initiated for at least 28 days following major surgery or until wound healing has occurred; hold for 28 days prior to major elective surgery
- The safety and efficacy of concurrent radiotherapy and bevacizumab has not been established
- Use bevacizumab with caution in:
    - Elderly patients
    - Patients with recurrent hemoptysis (>2.5ml), serious hemorrhage, or with squamous NSCLC
    - Patients with coagulopathies (congenital, acquired or therapeutic)
    - Patients with colorectal cancer and colorectal stents; increased risk of GI perforation has been reported
    - Patients given concurrent bisphosphonates or other anti-angiogenic agents, given increased risk of ONJ
- Capecitabine contains lactose and should not be used in patients with hereditary galactose/glucose/lactase disorders.

Pregnancy/Lactation:

- This regimen is **contraindicated** 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 **contraindicated** 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: Yes

back to top

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

- CBC; Baseline and before each cycle
- Liver and renal function tests; Baseline and before each cycle
- Electrolytes, including magnesium; Baseline and before each cycle
- INR and/or PT; Baseline and as clinically indicated if on anticoagulants
- Blood pressure; Baseline and every 2-3 weeks during therapy; more frequently in patients who develop hypertension
- Urine dipstick, 24 hour urine collection is recommended for patients with a 2+ or greater urine dipstick; Baseline and at each visit
- Dental evaluation; Baseline
- Clinical toxicity assessment of GI effects, dehydration, neurotoxicity, infection, bleeding, thromboembolism, hypersensitivity, injection site reaction, rash, hand-foot syndrome, perforation, fistula, ONJ, delayed wound healing, hypertension, cardiac, respiratory and ophthalmic effects; at each visit
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

Suggested Clinical Monitoring

- Cardiac function tests (Echo, RNA and/or MUGA scans) especially in patients who are close to the lifetime cumulative dose of anthracyclines/ anthracenediones; Baseline and as clinically indicated

back to top

J - Administrative Information

Outpatient prescription for home administration (capecitabine)

Approximate Patient Visit	2.5 to 3 hours
Pharmacy Workload (average time per visit)	23.653 minutes
Nursing Workload (average time per visit)	54.167 minutes

back to top

K - References

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PEBC Advice Documents or Guidelines

- Strategies of Sequential Therapies in Unresectable, Metastatic Colorectal Cancer Treated with Palliative Intent
- Continuous versus Intermittent Chemotherapy Strategies in Inoperable, Advanced Colorectal Cancer
- The Role of Primary Tumour Location in the Selection of Biologics for the Treatment of Unresectable Metastatic Colorectal Cancer

November 2023 Modified Pregnancy/lactation section

back to top

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.

Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

Regimen Monographs

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

The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.

The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.

Some Formulary documents, such as the medication information sheets, regimen information sheets and symptom management information (for patients), are intended for patients. Patients should always consult with their healthcare provider if they have questions regarding any information set out in the Formulary documents.

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back to top