Regimen Monograph

A - Regimen Name

CAPETUCA+TRAS Regimen

Capecitabine - Tucatinib - Trastuzumab

Disease Site

Breast

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 HER2-positive locally advanced unresectable or metastatic breast cancer, in patients who have received prior treatment with trastuzumab, pertuzumab and trastuzumab emtansine (T-DM1)*, separately or in combination, and have a good performance status

*Prior trastuzumab deruxtecan treatment may be considered as an alternative to T-DM1 (pending NDFP prior approval).

Supplementary Public Funding

capecitabine
ODB - General Benefit (capecitabine) (ODB formulary)

trastuzumab
New Drug Funding Program (Trastuzumab (Biosimilar) with Tucatinib and Capecitabine - Metastatic Breast Cancer) (NDFP Website)

tucatinib
Exceptional Access Program (tucatinib - in combination with trastuzumab and capecitabine for advanced breast cancer, according to clinical criteria) (EAP Website)

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B - Drug Regimen

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

Cycle 1:

capecitabine	1000 mg /m²	PO	BID, Days 1 to 14
tucatinib	300 mg	PO	BID continuously
trastuzumab	8 mg /kg	IV loading dose	Day 1 (cycle 1)

Cycle 2 and onwards:

capecitabine	1000 mg /m²	PO	BID, Days 1 to 14
tucatinib	300 mg	PO	BID continuously
trastuzumab	6 mg /kg	IV maintenance dose	Day 1

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

Until disease progression or unacceptable toxicity

Treatment with trastuzumab may continue if tucatinib or capecitabine are discontinued due to unacceptable toxicity.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal
No routine prophylaxis for capecitabine

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

Routine pre-medication is not recommended for trastuzumab. Refer to the "Management of Infusion-Related Reactions" table on pre-medications at re-challenge.

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 (eg. loperamide) should be initiated as medically appropriate, as early as possible.
- Also refer to CCO Antiemetic Recommendations.

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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.

Patients with brain metastases requiring immediate local therapy should undergo local CNS directed therapy prior to being treated with tucatinib, if appropriate.

If trastuzumab and capecitabine are both discontinued, tucatinib must also be discontinued.

Dosage with toxicity

Capecitabine

- Do not start treatment with capecitabine unless baseline neutrophil counts are ≥ 1.5 x 10^9/L and/or platelet counts of ≥ 100 x 10^9/L.
- Patients should be informed of the need to interrupt treatment immediately if moderate or severe toxicity occurs. Supportive care should be provided, including loperamide for diarrhea.
- Doses should not be re-escalated if reduced for toxicity.
- Missed or omitted doses of capecitabine should not be replaced.
- Dose modifications are mandatory for gastrointestinal, dermatological toxicity and hyperbilirubinemia. Practitioner may elect not to reduce dose for other toxicities unlikely to become serious or life-threatening.

Non-hematologic 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	Hold until resolved to ≤ grade 1	100%
2nd appearance	Hold until resolved to ≤ grade 1	75%
3rd appearance	Hold until resolved to ≤ grade 1	50%
4th appearance	Discontinue treatment permanently	Not applicable
Grade 3		
1st appearance	Hold until resolved to ≤ grade 1	75%
2nd appearance	Hold until resolved to ≤ grade 1	50%
3rd appearance, OR any evidence of Stevens-Johnson syndrome or Toxic epidermal necrolysis	Discontinue treatment permanently	Not applicable

Grade 4 1st appearance, including SJS or TEN, OR cardiotoxicity OR acute renal failure	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 OR 50%
2nd appearance OR any occurrence of confirmed leukoencephalopathy	Discontinue permanently	Not applicable

Hematologic Toxicity:

Hold capecitabine during a treatment cycle in the presence of grade 3 or 4 hematologic toxicity.

Tucatinib and Trastuzumab

Dose Level	Tucatinib Dose (mg/BID)
0	300
-1	250
-2	200
-3	150
-4	Permanently discontinue

Non-Hematologic Toxicity:

Toxicity	Grade	Tucatinib Dose	Trastuzumab Dose
Diarrhea, nausea / vomiting	Grade 3, without optimal antidiarrheal or antiemetics treatment	Initiate appropriate medical therapy. Hold until recovery to ≤ grade 1 or pretreatment level. Restart at same dose level.	Initiate appropriate medical therapy. Hold until recovery to ≤ grade 1 or pretreatment level. Restart at same dose.
	Grade 3, with optimal antidiarrheal or antiemetics treatment	Intensify appropriate medical therapy. Hold until recovery to ≤ grade 1 or pretreatment level. Restart at 1 dose level ↓.	Hold until recovery to ≤ grade 1 or pretreatment level. Restart at same dose.
	Grade 4	Permanently discontinue	
Rash	Grade 3, without optimal use of topical corticosteroids or anti-infectives.	Initiate appropriate medical therapy. Hold until recovery to ≤ grade 1 or pretreatment level. Restart at same dose level.	Initiate appropriate medical therapy. Hold until recovery to ≤ grade 1 or pretreatment level. Restart at same dose.
	Grade 3, with optimal use of topical corticosteroids or anti-infectives.	Hold until recovery to ≤ grade 1 or pretreatment level. Restart at 1 dose level ↓.	Hold until recovery to ≤ grade 1 or pretreatment level. Restart at same dose.
	Grade 4	Permanently discontinue	
Hepatotoxicity	Bilirubin >1.5 to 3 x ULN	Hold until recovery to ≤ grade 1 . Restart at same dose level.	Hold until recovery to ≤ grade 1 or pretreatment level. Restart at same dose.

	ALT or AST > 5 to 20 x ULN OR Bilirubin > 3 to 10 x ULN	Hold until recovery to ≤ grade 1. Restart at 1 dose level ↓.	
	ALT and/or AST > 20 x ULN OR Bilirubin > 10 x ULN	Permanently discontinue	
	ALT or AST > 3 x ULN AND Bilirubin > 2 x ULN		
Other Adverse Reactions*	Grade 3	Hold until recovery to ≤ grade 1. Resume at 1 dose level ↓.	Hold until recovery to ≤ grade 1. Restart at same dose level.
	Grade 4	Permanently discontinue	

*No dose modifications are required for alopecia

Trastuzumab Hematologic Toxicity:

Dosage with myelosuppression*:* No adjustment required for myelosuppression.

Trastuzumab Cardiotoxicity:

Product Monograph Recommendations

- Trastuzumab should be held with a fall in LVEF (if LVEF falls ≥10 points from baseline and/or if LVEF falls to < 50%). Repeat LVEF in 3 weeks and consider discontinuing. Discontinue if clinically significant cardiac dysfunction or cardiac failure develops.

Canadian Consensus Guidelines

- Discontinue if symptomatic.

Management of trastuzumab therapy in adjuvant breast cancer patients with asymptomatic decreases in LVEF (Mackey et al 2008):

Relationship of LVEF to Lower Limit of Normal (LLN)	Trastuzumab dose modification based on asymptomatic LVEF decrease from baseline		
	≤ 10 percentage points	**10-15 percentage points**	**≥ 15 percentage points**
Within facility's normal limits	Continue	Continue	**Hold** and repeat MUGA/ECHO after 4 weeks
1-5% below LLN	Continue [1]	**Hold** and repeat MUGA/ECHO after 4 weeks [1, 2]	**Hold** and repeat MUGA/ECHO after 4 weeks [2, 3]
≥ 6% below LLN	Continue and repeat MUGA/ECHO after 4 weeks [3]	**Hold** and repeat MUGA/ECHO after 4 weeks [2, 3]	**Hold** and repeat MUGA/ECHO after 4 weeks [2, 3]

[1] Consider cardiac assessment and starting ACEI therapy.

[2] After 2 holds, consider permanent trastuzumab discontinuation.

[3] Start ACEI therapy and refer to cardiologist.

Trastuzumab - Dosage with Other Toxicity:

Toxicity	Action
Pulmonary Toxicity	Discontinue permanently and manage symptoms aggressively with beta-agonists, antihistamines and/or corticosteroids. Discontinue permanently and do not re-challenge.

Management of Infusion-related reactions (trastuzumab):

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 rate. • Manage the symptoms. **Restart:** • Once symptoms have resolved, if IR was not severe, consider resuming the infusion at a slower rate.	• Restart and re-challenge with pre-medications (e.g. H1-receptor antagonist and corticosteroid).
3 or 4	• Stop treatment. • Aggressively manage symptoms.	• Discontinue permanently (do not re-challenge).

Hepatic Impairment

Hepatic impairment	Capecitabine Starting Dose	Trastuzumab Dose	Tucatinib Starting Dose
Child Pugh A or B	No dose adjustment necessary	No dose adjustment necessary	No dose adjustment necessary
Child Pugh C	No data, has not been studied		200 mg BID

Renal Impairment

Creatinine Clearance (mL/min)	Capecitabine (% of Starting Dose)	Trastuzumab Dose	Tucatinib Starting Dose
51 - 80	100 % with close monitoring	No dosage adjustment necessary	No dosage adjustment necessary
30 - 50	75 % (use with caution)		
<30	Discontinue		Use is not recommended

Dosage in the Elderly

No dose adjustment is required for patients on capecitabine, trastuzumab and tucatinib.

Capecitabine:

Older patients (≥ 65 years) are more susceptible to the effects of fluoropyrimidine-based therapies with increased grade 3/4 adverse effects, especially when used in combination.

Trastuzumab:

The risk of cardiac dysfunction and myelosuppression may be increased in elderly patients. The reported trials did not determine differences in efficacy between patients ≥ 65 years versus younger patients.

Tucatinib:

No overall differences in effectiveness was observed in patients ≥ 65 years compared to younger patients. Patients ≥ 65 years were more likely to experience a serious adverse event such as diarrhea and vomiting and more likely to discontinue treatment compared to younger patients <65 years.

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F - Adverse Effects

Refer to capecitabine, tucatinib, trastuzumab 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
• Diarrhea • Hand-foot syndrome • Nausea, vomiting	• Fatigue • ↑ LFTs • Mucositis • Anorexia, weight loss	• Anemia • Rash • ↑ Bilirubin • Musculoskeletal pain • Creatinine increased • Peripheral neuropathy • Epistaxis • Headache • Hypokalemia • Abdominal pain • Constipation • Cough, dyspnea • Dizziness • Dyspepsia • Infection	• Cardiotoxicity • Arrhythmia • Arterial / venous thromboembolism • Hypersensitivity • Myelosuppression ± infection, bleeding • Leukoencephalopathy • Hepatic failure • GI perforation, obstruction • Leukoencephalopathy • Idiopathic thrombocytopenic purpura • Eye disorders • Nephrotoxicity • Pancreatitis • Interstitial lung disease • Secondary malignancy • Seizure

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G - Interactions

Refer to capecitabine, tucatinib, trastuzumab drug monograph(s) for additional details.

- Concomitant administration of capecitabine with sorivudine or analogues is **contraindicated**, given increased risk of capecitabine toxicity (may be fatal). Wait at least 4 weeks after sorivudine treatment before starting capecitabine.
- Avoid concomitant administration of capecitabine with phenytoin as capecitabine may increase phenytoin levels. Monitor phenytoin levels if co-administered.
- Caution and monitor INR/PT when capecitabine is co-administered with warfarin.
- Caution and monitor for reduced effectiveness of capecitabine when co-administered with proton-pump inhibitors. Consider switching to an antacid if appropriate.
- Avoid concomitant administration of tucatinib and moderate or strong CYP2C8 inducers and strong CYP3A4 inducers.
- Avoid concomitant administration of tucatinib and strong CYP2C8 inhibitors. If co-administration is unavoidable, reduce tucatinib starting dose to 100 mg twice daily and increase monitoring for tucatinib-related toxicity. After discontinuation of the strong CYP2C8 inhibitor for 3 elimination half-lives, resume tucatinib at dose taken prior to initiating the inhibitor. If co-administered with a moderate inhibitor, increase monitoring for toxicity.
- Avoid concomitant administration of tucatinib and CYP3A4 substrates. If co-administration is unavoidable, consider dose modification of CYP3A substrates with narrow therapeutic indices and/or increased monitoring for potential adverse reactions.
- Caution when co-administered tucatinib with P-gp substrates with narrow therapeutic indices. Refer to the prescribing information of sensitive P-gp substrates for dose adjustment recommendations.
- Avoid concomitant administration of trastuzumab with anthracyclines and other cardiotoxic drugs. Use extreme caution with anthracyclines for up to 28 weeks after stopping trastuzumab.

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H - Drug Administration and Special Precautions

Refer to capecitabine, tucatinib, trastuzumab drug monograph(s) for additional details

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

Administration: 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.

Administration: tucatinib

- Swallow tablets whole, do not chew, crush, or split prior to swallowing.
- Take approximately 12 hours apart at the same time each day with or without a meal.
- Tucatinib and capecitabine may be taken at the same time.
- If a dose is missed or vomited, administer the next dose at its usual time.
- Store original container at a controlled room temperature between 20ºC and 25ºC
- Protect from moisture.

Administration: trastuzumab

- Different trastuzumab products are **NON-INTERCHANAGEABLE**. There have been fatal reports where the incorrect trastuzumab product (e.g. **trastuzumab emtansine** instead of trastuzumab) was administered to patients with breast cancer in the clinical trials setting.
- DO NOT ADMINISTER AS AN IV PUSH OR BOLUS.
- Mix in 250 mL bag NS. Do not use D5W as it causes protein aggregation. Do not shake.
- Administer loading dose over 90 minutes. Observe during the infusion and for at least 90 minutes after the infusion.
- If no previous IR, subsequent infusions may be administered over 30 minutes. Observe patients during the infusions and for at least 30 minutes after the infusions.
- Should not be mixed or diluted with other drugs.
- Compatible with polyvinylchloride, polyethylene or polypropylene bags.
- Diluent supplied - Bacteriostatic Water for Injection (BWFI) - contains benzyl alcohol 1.1%; if patient is hypersensitive to benzyl alcohol, may reconstitute with Sterile Water for Injection, but must be used immediately and discard unused portion.
- Solution reconstituted with the supplied BWFI is stable up to 28 days refrigerated.
- Do not freeze the reconstituted solution.
- Missed Dose
    - If a dose is missed by 1 week or less, the product monograph recommends the usual maintenance dose (2 mg/kg if on a weekly schedule or 6 mg/kg if on an every-3-week schedule) should be administered as soon as possible (do not wait until the next planned cycle) and subsequent maintenance doses should be administered 7 or 21 days later (based on patient's maintenance dose/schedule)
    - If a dose is missed by >1 week*, the product monograph recommends a re-loading dose (4 mg/kg if patient receives trastuzumab weekly; 8 mg/kg if on an every-3-week schedule) should be administered (over 90 minutes) as soon as possible, followed by the usual maintenance dose administered 7 or 21 days later (based on patient's maintenance dose/schedule).

      *For every 3-week dosing, consider repeating the loading dose for treatment delays ≥ 3 weeks (i.e.≥ 6 weeks from last dose). [Breast Disease Site Group consensus].

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, its excipients, 5FU or any ingredient in the formulation or component of the container.
- Patients who are hypersensitive to tucatinib or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.
- Patients with known hypersensitivity to trastuzumab, Chinese Hamster Ovary (CHO) cell proteins, or any components of the product.
- Patients with known near or complete absence of DPD (dihydropyrimidine dehydrogenase) activity. Refer to the DPD Deficiency Guidance for Clinicians for more information.
- Concomitant use of capecitabine with sorivudine or related analogues (i.e. brivudine), given potential fatal drug interaction.
- Patients with severe renal impairment (CrCl <30 mL/min).

Other Warnings/Precautions:

- Trastuzumab should only be used in patients whose tumours overexpress HER2.
- Use with caution in patients with known chronic liver disease, carriers of hepatitis B or C or with pre-existing liver function test abnormalities (total bilirubin > 1.5 × ULN, or AST/ALT > 2.5 × ULN, or AST/ALT > 5 × ULN if liver metastases were present) as they were excluded from clinical trials.
- Patients with risk factors for dehydration, pre-existing renal dysfunction or on nephrotoxic agents.
- Patients with partial DPD deficiency - use with extreme caution. Refer to the DPD Deficiency Guidance for Clinicians for more information.
- Patients with a history of cardiovascular disease.
- The risk of cardiotoxicity must be weighed against the potential benefits of treatment, especially in older patients, patients with pre-existing cardiac disease (including LVEF < 55%) and patients who have had prior cardiotoxic therapy. Note: in the adjuvant trials, patients with cardiac risk factors were excluded from the trials.
- Exercise caution in patients with pre-existing pulmonary disease or patients with extensive pulmonary tumour involvement, as they may experience more severe lung toxicities.
- Use with caution before or after anthracyclines (for up to 28 weeks after trastuzumab discontinuation due to long half-life).
- Capecitabine contains lactose; carefully consider use in patients with hereditary galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption

- Patients should exercise caution when driving or operating a vehicle or potentially dangerous machinery.

Pregnancy / 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: Probable

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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

- CBC; Baseline and before each cycle
- Liver function tests; Baseline, every 3 weeks during treatment and as clinically indicated
- Renal function tests; Baseline and before each cycle
- Cardiac assessment, including evaluation of left ventricular function (Echocardiogram or MUGA scan); Baseline, q3 months during treatment, then q6 months after trastuzumab discontinuation x2 years (and annually up to 5 years after last trastuzumab dose in adjuvant breast cancer patients who received anthracyclines), or longer if continued LVEF decrease, also as clinically indicated (more frequent monitoring in asymptomatic LVEF reductions)
- INR and/or PT; Baseline and as clinically indicated if patient is on anticoagulants

- Infusion-associated symptoms with trastuzumab; During the infusion and observe for at least 90 minutes afterwards (for loading dose), and at least 30 minutes afterwards (maintenance dose)
- Clinical toxicity assessment for fatigue, gastrointestinal effects, cutaneous reactions (especially hand-foot syndrome), infection, anemia, bleeding, cardiac failure, pulmonary toxicity, neuropathy or seizure; As clinically indicated
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

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J - Administrative Information

Outpatient prescription for home administration (capecitabine and tucatinib)

Approximate Patient Visit	First cycle: 1.5 hours; Subsequent cycles: 0.5 hour
Pharmacy Workload (average time per visit)	19.589 minutes
Nursing Workload (average time per visit)	48.333 minutes

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K - References

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CADTH reimbursement recommendation (Tucatinib: in combination with trastuzumab-capecitabine for the treatment of patients with locally advanced unresectable or metastatic HER2-positive breast cancer), November 2021.

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Murthy RK, Loi S, Okines A, et al. Tucatinib, trastuzumab, and capecitabine for HER2-positive metastatic breast cancer. N Engl J Med 2020; 382:597-609.

Schaller G, Fuchs I, Gonsch T, et al. Phase II study of capecitabine plus trastuzumab in human epidermal growth factor receptor 2 overexpressing metastatic breast cancer pretreated with anthracyclines or taxanes. J Clin Oncol. 2007;25(22):3246-50.

Supplementary Appendix to: Murthy RK, Loi S, Okines A, et al. Tucatinib, trastuzumab, and capecitabine for HER2-positive metastatic breast cancer. N Engl J Med 2020;382:597-609. DOI: 10.1056/NEJMoa1914609.

February 2025 Updated Pregnancy and Lactation 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.

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.

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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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