Cancer Care Ontario
Action Cancer Ontario

NEW DRUG FUNDING PROGRAM (NDFP) & EVIDENCE BUILDING PROGRAM (EBP)

Approved Drugs and Eligibility Criteria

The information in this document is a summary of the funding criteria for the New Drug Funding Program and the Evidence Building Program. It is updated on a regular basis. Although we strive to ensure that all information is accurate at the time of posting, some items may be subject to change from time-to-time. Confirmation that patients meet eligibility criteria in CCO eClaims is required at the time of enrolment. The information contained herein is intended to be for informational purposes only. It is not intended to constitute medical advice and should not be relied upon in any such regard. The information contained herein does not create a physician-patient relationship between Cancer Care Ontario and you. Cancer Care Ontario does not recommend the use of any drug or treatment method described in this document. Anyone using the information does so at his or her risk. Any use of the information is subject, at all times, to Cancer Care Ontario's Terms and Conditions. For detailed information on treatments, consult a qualified healthcare professional.

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New Drug Funding Program (NDFP)

The New Drug Funding Program (NDFP), created in 1995, is a publicly funded drug program under the Ontario Public Drug Programs (OPDP). NDFP directly covers the cost of many newer, and often very expensive, injectable cancer drugs administered in hospitals and cancer centres.

Eligibility – NDFP

Patients must be residents of Ontario and have a valid Ontario Health Card. Reimbursement is for the drug costs for patients who meet the NDFP eligibility criteria for the specific approved injectable cancer drug.

Completed enrolment forms and supporting clinical documents (when required), must be submitted by the prescribing physicians before treatments begin. All eligibility criteria must be met as specified. Treatment claims and supporting documentation, if applicable, must be submitted to Cancer Care Ontario according to the monthly submission schedule. All enrolment forms, treatment claims and supporting clinical documents, must be submitted through CCO eClaims.

Reimbursement for Cancer Drugs

- NDFP funds new and expensive hospital-based injectable cancer drugs that have been evaluated and approved for coverage.
- NDFP funds the majority of IV cancer drug costs in Ontario, while the remainder is covered by the Systemic Treatment Funding Model mainly for older cancer drugs that were approved before the establishment of the NDFP.
- Treatments administered in the inpatient setting are not eligible for funding via NDFP, with the exception of arsenic trioxide for acute promyelocytic leukemia.
- NDFP does not fund cancer drugs administered in private clinics.
- NDFP does not reimburse individuals or retail pharmacies for the cost of cancer drugs. Instead, reimbursements are made to Ontario's regional cancer centres and more than 80 community hospitals.
- Reimbursement is for the drug costs of those patients who meet the eligibility criteria for the specific approved drugs.
- NDFP is developing a policy on the reimbursement for cancer drugs for patients who are within the context of clinical trials. A draft policy is available on the **NDFP website**.

Evidence Building Program (EBP)

The Evidence-Building Program (EBP) complements and strengthens Ontario's New Drug Funding Program (NDFP) and the process for making drug funding decisions in Ontario by maintaining rigour and consistency. The EBP seeks to resolve uncertainty around clinical and cost-effectiveness data related to the expansion of cancer drug coverage within Ontario.

For a cancer drug to be included in Ontario's EBP there must be evolving, but incomplete evidence of benefits. This will allow us to fund the drug on a time-limited basis to collect real-world data on its clinical and cost effectiveness. This data will be used by the Ministry of Health and Long-Term Care to help inform a final change to existing funding criteria.

Eligibility – EBP

To receive drug coverage under the EBP, patients must be residents of Ontario and have a valid Ontario Health Card. Reimbursement is for the drug costs of those patients who meet the EBP eligibility criteria for the specific approved cancer drug.

Completed enrolment forms and supporting clinical documents (when required), must be submitted by the prescribing physicians before treatments begin. All eligibility criteria must be met as specified. Treatment claims and supporting documentation, if applicable, must be submitted to Cancer Care Ontario according to the monthly submission schedule. All enrolment forms, treatment claims and supporting clinical documents, must be submitted through CCO eClaims.

Supplemental Forms – EBP

As a condition of participating in the EBP, Supplemental Forms are required and must be submitted at specific time intervals to ensure continued reimbursement. Supplemental Forms are also required following the completion of therapy to facilitate continued real-world data collection, in order to conduct analyses to inform permanent funding decisions. Please see Supplemental Forms for respective EBP drugs in CCO eClaims for additional detail.

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Funded Drugs and Eligibility Criteria under NDFP

The following is a list of drugs and indications that are approved for reimbursement in NDFP. All information corresponds to the most current enrolment forms found in CCO eClaims, including funded dose, regimen, schedule, and other eligibility criteria. Note that ALL criteria must be met to be eligible for reimbursement, unless otherwise specified.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Aldesleukin (all-dess-LOO-kin) Other name: Proleukin®	In-Transit Metastases from Melanoma	The patient has in-transit metastases from melanoma and has failed or is not a candidate for surgery or other treatments	• 1 vial (22 million IU) of aldesleukin will be funded per cycle for intralesional injection	NDFP funding is for patients who receive aldesleukin as an intralesional injection. This drug may be referred to as aldesleukin or interleukin-2.
Arsenic Trioxide (AR-se-nik tri-OX-ide) Other name: Trisenox®	First Line Induction of Acute Promyelocytic Leukemia (APL)	Arsenic trioxide will be used in combination with all-trans retinoic acid (ATRA) in the first-line setting for acute promyelocytic leukemia (APL) as an induction treatment	Low to Intermediate Risk (WBC ≤ 10 x 10^9/L) • Arsenic trioxide is administered intravenously at a dose of 0.15 mg/kg daily until complete remission. High Risk (WBC > 10 x 10^9/L) • Arsenic trioxide is administered intravenously at a dose of 0.15 mg/kg daily on days 9 to 36	A separate enrolment is required for consolidation treatment with arsenic trioxide. Arsenic must be administered with ATRA. The ATRA portion is not funded by CCO and therefore, it is advised that sites confirm ATRA will be covered by another funding source prior to initiation of therapy.
Arsenic Trioxide (AR-se-nik tri-OX-ide) Other name: Trisenox®	Relapsed/Refractory Induction of Acute Promyelocytic Leukemia (APL)	Arsenic trioxide will be used in combination with all-trans retinoic acid (ATRA) in the relapsed/refractory setting for acute promyelocytic leukemia (APL) as an induction treatment.	Low to Intermediate Risk (WBC ≤ 10 x 10^9/L) • Arsenic trioxide is administered intravenously at a dose of 0.15 mg/kg daily until complete remission. High Risk (WBC > 10 x 10^9/L) • Arsenic trioxide is administered intravenously at a dose of 0.15 mg/kg daily on days 9 to 36	A separate enrolment is required for consolidation treatment with arsenic trioxide. Arsenic must be administered with ATRA. The ATRA portion is not funded by CCO and therefore, it is advised that sites confirm ATRA will be covered by another funding source prior to initiation of therapy.
Arsenic Trioxide (AR-se-nik tri-OX-ide) Other name: Trisenox®	First Line Consolidation of Acute Promyelocytic Leukemia (APL)	Arsenic trioxide will be used in combination with all-trans retinoic acid (ATRA) in the first-line setting for acute promyelocytic leukemia (APL) as a consolidation treatment	Low to Intermediate Risk (WBC ≤ 10 x 10^9/L): • Arsenic trioxide is administered intravenously at a dose of 0.15 mg/kg/day for 5 days per week, 4 weeks on and 4 weeks off, for a total of 4 cycles. High Risk (WBC > 10 x 10^9/L): Two cycles of arsenic trioxide, are administered as follows: • Cycle 1: arsenic trioxide 0.15 mg/kg/day intravenously days 1-28 • Cycle 2: arsenic trioxide 0.15 mg/kg/day intravenously on days 1 to 5, 8 to 12, 15 to 19, 22 to 26, 29 to 33	Arsenic must be administered with ATRA. The ATRA portion is not funded by CCO and therefore, it is advised that sites confirm ATRA will be covered by another funding source prior to initiation of therapy.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Arsenic Trioxide (AR-se-nik tri-OX-ide) Other name: Trisenox®	Relapsed/Refractory Consolidation of Acute Promyelocytic Leukemia (APL)	Arsenic trioxide will be used in combination with all-trans retinoic acid (ATRA) in the relapsed/refractory for acute promyelocytic leukemia (APL) as a consolidation treatment	Low to Intermediate Risk (WBC ≤ 10 x 10^9/L): • Arsenic trioxide is administered intravenously at a dose of 0.15 mg/kg/day for 5 days per week, 4 weeks on and 4 weeks off, for a total of 4 cycles. High Risk (WBC > 10 x 10^9/L): Two cycles of arsenic trioxide, are administered as follows: • Cycle 1: arsenic trioxide 0.15 mg/kg/day intravenously days 1-28 • Cycle 2: arsenic trioxide 0.15 mg/kg/day intravenously on days 1 to 5, 8 to 12, 15 to 19, 22 to 26, 29 to 33	Arsenic must be administered with ATRA. The ATRA portion is not funded by CCO and therefore, it is advised that sites confirm ATRA will be covered by another funding source prior to initiation of therapy.
Azacitidine (ay-za-SYE-ti-deen) Other Name: Vidaza®	Acute Myeloid Leukemia (AML)	For the treatment of adult patients who are not eligible for hematopoietic stem cell transplantation with Acute Myeloid Leukemia (AML) with 20-30% blasts and multi-lineage dysplasia, according to World Health Organization (WHO) classification	Intended dosing schedule (repeated every 28 days; 1 cycle = every 28 days) 75 mg/m^2 sc daily for 7 consecutive days, or 75 mg/m^2 sc daily for 6 consecutive days, or 75 mg/m^2 sc 5-2-2 (5 consecutive days of treatment, followed by 2 consecutive days without treatment, and then 2 consecutive days of treatment every 28 days)	The NDFP will only fund the regimens listed on the form, as per Ministry criteria. An exception is the one-off situation that may occur (e.g. statutory holidays). Sites are encouraged to contact the NDFP should there be questions relating to the one-off scenarios. Evidence of eligibility must be demonstrated either with a bone marrow aspirate or biopsy, whichever report produces the worst percentage. The bone marrow aspirate or biopsy must be completed within 8 weeks of starting azacitidine. As part of reimbursement, sites are required to submit to the NDFP copies of the baseline bone marrow and cytogenetics report. If cytogenetics is inconclusive or not done, the patient may still meet criteria based on the IPSS score being intermediate-2 or higher by virtue of the percent blast count and the number of cytopenias. In certain situations, the provision of prior cytogenetics is sufficient if the MDS is confirmed by morphology and a) if IPSS score meets criteria without the need for cytogenetics, OR b) if blast count is 20-30%. Treatments will be funded as long as the patient continues to benefit or until disease progression.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Azacitidine (ay-za-SYE-ti-deen) Other Name: Vidaza®	Myelodysplastic Syndromes (MDS)	For treatment of adult patients who are not eligible for hematopoietic stem cell transplantation with Intermediate-2 and high-risk myelodysplastic syndrome (MDS) according to the International Prognostic Scoring System (IPSS)	Intended dosing schedule (repeated every 28 days; 1 cycle = every 28 days) 75 mg/m^2 sc daily for 7 consecutive days, or 75 mg/m^2 sc daily for 6 consecutive days, or 75 mg/m^2 sc 5-2-2 (5 consecutive days of treatment, followed by 2 consecutive days without treatment, and then 2 consecutive days of treatment every 28 days)	The NDFP will only fund the regimens listed on the form, as per Ministry criteria. An exception is the one-off situation that may occur (e.g. statutory holidays). Sites are encouraged to contact the NDFP should there be questions relating to the one-off scenarios. Evidence of eligibility must be demonstrated either with a bone marrow aspirate or biopsy, whichever report produces the worst percentage. The bone marrow aspirate or biopsy must be completed within 8 weeks of starting azacitidine. As part of reimbursement, sites are required to submit to the NDFP copies of the baseline bone marrow and cytogenetics report. If cytogenetics is inconclusive or not done, the patient may still meet criteria based on the IPSS score being intermediate-2 or higher by virtue of the percent blast count and the number of cytopenias. In certain situations, the provision of prior cytogenetics is sufficient if the MDS is confirmed by morphology and a) if IPSS score meets criteria without the need for cytogenetics, OR b) if blast count is 20-30%. Treatments will be funded as long as the patient continues to benefit or until disease progression.
Bendamustine (BEN-da-MUS-teen) Other Name: Treanda®	First line – Chronic Lymphocytic Leukemia	• Bendamustine is being used as first line therapy for the chronic lymphocytic leukemia • The patient has Binet Stage B or C and a WHO performance status of ≤ 2 at the recommended dose • The patient is not medically fit to tolerate fludarabine-based regimens and could be treat with other options such as chlorambucil	Bendamustine 100 mg/m^2 on Days 1 and 2 within each 28 day cycle to a maximum of 6 cycles	Bendamustine funding is for single agent use only.
Bendamustine (BEN-da-MUS-teen) Other Name: Treanda®	First Line - Indolent Non-Hodgkin's Lymphoma and Mantle Cell Lymphoma	• Bendamustine is used in combination with rituximab in the first line setting in patients with indolent CD20 positive non-Hodgkin's lymphoma or mantle cell lymphoma • The patient has an ECOG performance status of less than or equal to 2	Bendamustine 90 mg/m^2 on Days 1 and 2 of a 28-day cycle to a maximum of 6 cycles (combination therapy)	Bendamustine is not funded if used as a single agent. Patients who receive first line rituximab bendamustine would be eligible for rituximab maintenance provided that the maintenance rituximab funding criteria are met.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Bendamustine (BEN-da-MUS-teen) Other Name: Treanda®	Relapsed/Refractory - Indolent Non-Hodgkin's Lymphoma and Mantle Cell Lymphoma	• Bendamustine is used in the relapsed/refractory setting in patients with indolent CD20 positive non-Hodgkin's lymphoma or mantle cell lymphoma **when used in combination with rituximab**, where the combination of fludarabine-rituximab could previously have been a therapeutic option	Bendamustine 90 mg/m^2 on Days 1 and 2 of a 28-day cycle to a maximum of 6 cycles (combination therapy)	Bendamustine is not funded if used as a single agent. A patient whose disease has relapsed from rituximab is eligible for rituximab funding provided that the funding criteria for rituximab retreatment are met (e.g., the patient has sustained a response and has remained treatment free for at least one year's duration following the last dose of rituximab received). Please refer to the rituximab retreatment eligibility form for details.
Bevacizumab (be-vuh-SIZ-uh-mab) Other name: Avastin®	First Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer	• To be used as combination therapy with the FOLFIRI or FOLFOX or XELOX regimens for the first line treatment of metastatic colorectal, small bowel, or appendiceal cancer. • The patient has metastatic colon, rectal, small bowel or appendiceal cancer. • The patient is being treated in the first line setting • The patient is receiving one of the following regimens as per NDFP criteria: FOLFIRI, FOLFOX, XELOX	Bevacizumab 5 mg/kg q14 days (with FOLFIRI or FOLFOX), or Bevacizumab 7.5 mg/kg q21 days (with XELOX)	1. To be used in combination with FOLFIRI, FOLFOX, or XELOX regimens only. Not reimbursed as a single agent. Not reimbursed if used in other lines of therapy or if used for other indications. 2. Initial funding is for 12 cycles. Patients must continue to demonstrate responding or stable disease in order to be eligible for subsequent cycles of bevacizumab (in increments of 12). Acceptable staging tests, which include results of the chest X-ray or CT scan of thorax for lung lesions and ultrasound or CT scan of abdomen for intra-abdominal lesions, must be provided to Cancer Care Ontario. 3. Switches between bevacizumab and panitumumab will only be considered within the first 3 months of starting therapy with either agent, provided there is no disease progression on treatment. Patients will only be approved for one switch (i.e. from bevacizumab to panitumumab or vice versa). Please upload a clinic note indicating the reason(s) for switching. 4. Patients whose disease progresses on panitumumab in the first line setting are not eligible for subsequent treatment with bevacizumab.
Bevacizumab (be-vuh-SIZ-uh-mab) Other name: Avastin®	Metastatic (Stage IVB), Persistent, or Recurrent Carcinoma of the Cervix	• Bevacizumab will be used in combination with chemotherapy[1, 2, 3, 4] for the treatment of patients with metastatic (Stage IVB), persistent or recurrent carcinoma of the cervix of all histological subtypes (except small cell)[5]; and	Bevacizumab 15mg/kg IV every 21 days.	1. Single agent bevacizumab is not funded. Bevacizumab is only funded if used with the following chemotherapy regimens: paclitaxel-carboplatin, paclitaxel-cisplatin, paclitaxel-topotecan. For more information on the dosing schedules, please refer to the list of evidence informed regimens for cervical cancer at

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		• The patient has an Eastern Cooperative Performance Status (ECOG) of ≤ 1		https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=300112. 2. Bevacizumab is only funded in the first line setting. Funding will continue until disease progression. Continued use of bevacizumab in patients whose disease has progressed while on a first line regimen will not be funded. 3. In situations where a treatment break has been taken, bevacizumab is only funded if the continuation of the same first line regimen is considered clinically appropriate. 4. In situations where chemotherapy needs to be started first, the later addition of bevacizumab will be funded provided that funding criteria are met at the time of treatment initiation and the patient's disease has not yet progressed while on chemotherapy. 5. Bevacizumab funding is intended for patients who are not candidates for other curative treatments (e.g., radiation, surgery). 6. The Systemic Treatment Funding Model will fund paclitaxel, carboplatin and cisplatin. Topotecan is note funded by CCO.
Bevacizumab (be-vuh-SIZ-uh-mab) Other name: Avastin®	Front-line Treatment (Previously Untreated) Ovarian, Fallopian Tube, and Primary Peritoneal Cancer (with paclitaxel and carboplatin)	• Bevacizumab is given in combination with paclitaxel and carboplatin for the front-line treatment of epithelial ovarian, fallopian tube or primary peritoneal cancer patients with high risk of relapse (stage III sub-optimally debulked*, or stage III unresectable, or stage IV patients) • Patient has Eastern Cooperative Oncology Group performance status (ECOG) <= 2 *Sub-optimal debulking is defined as patients who have > 1 cm of residual disease after debulking surgery.	• Paclitaxel 175 mg/m^2 every 3 weeks as an intravenous infusion for 6 cycles (to be used in combination with carboplatin). • Bevacizumab 7.5 mg/kg every 3 weeks as an intravenous infusion. • Bevacizumab will be funded with cycles 2-6 of chemotherapy, and as maintenance treatment for up to 12 additional cycles or until disease progression, whichever comes first (i.e., a maximum of 17 bevacizumab cycles per patient [1 cycle = 1 dose]).	1. Neoadjuvant use of bevacizumab or use of bevacizumab in patients who are deemed resectable at initial diagnosis will not be funded. 2. Bevacizumab is only funded if used in combination with carboplatin and paclitaxel given together once every 3 weeks (CRBPPACL+BEVA). For more information on the dosing schedules, please refer to the list of evidence informed regimens for ovarian cancer at https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=300150. 3. Funding is for a maximum of 17 cycles of bevacizumab or until disease progression, whichever comes first.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Blinatumomab (blin-a-too-moo-mab) Other name: Blincyto®	Acute Lymphoblastic Leukemia	• Blinatumomab is used for treatment of adult patients with Philadelphia chromosome negative relapsed or refractory B precursor acute lymphoblastic leukemia (ALL) and who have had at least two prior lines of therapy.	• Cycle 1: Blinatumomab 9 mcg/day for days 1-7, followed by 28 mcg per day for 21 days, followed by a 14 day treatment-free interval. • Cycles 2-5: Blinatumomab 28 mcg/day days 1-28 each, followed by a 14 day treatment-free interval.	1. NDFP will provide coverage of blinatumomab in both the inpatient and outpatient settings, provided that funding criteria are met. 2. CCO recognizes that the amount of drug used to prepare the IV solution for infusion exceeds the amount that is infused into the patient due to the unique preparation method (i.e., an "overfill" of drug is required to account for the priming of the IV line and to ensure that the patient will receive the prescribed dose of blinatumomab). This "overfill" amount will be automatically captured in eClaims according to the treatment doses submitted (please refer to the funding announcement for details).
Bortezomib (bore-TEH-zo-mib) Other name: Velcade®	Previously Untreated Multiple Myeloma – Pre-Stem Cell Transplant	The patient has newly diagnosed multiple myeloma and is eligible for autologous stem cell transplantation[a] Bortezomib is used as a component of induction therapy pre-autologous stem cell transplantation (ASCT)[b]	Bortezomib must be used as part of combination therapy. Funded doses may include either of the following: Bortezomib 1.3 mg/m^2 IV or sc Days 1, 4, 8, and 11 of each cycle for 4 cycles[c] (1 cycle = 21 days), or Bortezomib 1.5 mg/m^2 IV or sc weekly on Days 1, 8, 15, and 22 of each cycle for 4 cycles[c] (1 cycle = 28 days)	The patient must not have received prior therapy (e.g., dexamethasone, chemotherapy, or 17mmunomodulatory-based therapy) for multiple myeloma. Bortezomib-based combination therapy can include the addition of dexamethasone, alkylator or anthracycline chemotherapy, or 17mmunomodulatory-based therapy to the bortezomib backbone. For additional doses, prior authorization is required.
Bortezomib (bore-TEH-zo-mib) Other name: Velcade®	Previously Untreated – Multiple Myeloma	The patient has previously untreated multiple myeloma and is unsuitable for stem cell transplantation Bortezomib will be given as part of a combination therapy	Bortezomib will be given as a part of the VMP regimen (bortezomib, melphalan and prednisone) for up to a maximum of 9, six week cycles. The bortezomib dose is 1.3 mg/m^2 IV or SC, given on days 1, 4, 8, 11, 22, 25, 29, 32 on a six week cycle for cycles 1 to 4; and given on days 1, 8, 22, 29 on a six week cycle for cycles 5 to 9. Patients who are not able to tolerate the twice weekly bortezomib schedule may be switched to (or initially offered) the once weekly bortezomib schedule (Blood. 2010; 116(23):4745-4743). The once weekly bortezomib dose is 1.3 mg/m^2 (as part of the VMP regimen) on days 1, 8, 15 and 22 every 35 days (cycles 1-9). **A minimum of 72 hours** is required between bortezomib doses.	N/A

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Bortezomib (bore-TEH-zo-mib) Other name: Velcade®	Relapsed or Refractory Multiple Myeloma	One of the following criteria must be met: The patient has multiple myeloma that is refractory to or has relapsed within one year of the conclusion of initial or subsequent treatment(s) and is suitable for further chemotherapy The patient has relapsed at least one year after autologous stem cell transplantation	1.3 mg/m^2 IV or SC twice weekly for 2 weeks (Days 1, 4, 8 and 11) followed by a 10 day rest period (Days 12-21) for eight q3 week cycles, followed by treatment on days 1, 8, 15, and 22 q5 weeks[a,b], or Weekly 1.3 mg/m^2	a. Bortezomib dosing based on the APEX trial (NEJM 2005; 352:2487-98). b. Regimen modifications require prior approval. Retreatment for patients having previously received bortezomib through the NDFP will not be reimbursed.
Brentuximab (bren-tuk-see-mab) Other name: Adcertis®	Hodgkin's Lymphoma	Brentuximab will be used in patients with Hodgkin's lymphoma who have relapsed disease following autologous stem cell transplant (ASCT) and who have an ECOG performance status of 0 or 1.	Brentuximab 1.8 mg/kg IV every 3 weeks until disease progression or unacceptable toxicity.	A clinic note confirming relapse post autologous stem cell transplantation and a pathology report confirming CD30+ve Hodgkin's lymphoma must be submitted to CCO prior to the start of treatment. Treatments beyond 16 cycles require documentation showing continued evidence of benefit (i.e., a clinic note and CT scan confirming that there is no evidence of disease progression). The documentation can be submitted with the treatment claims. Patients who are not candidates for ASCT and who have relapsed disease following at least two prior multi-agent chemotherapies are not eligible for brentuximab funding. Use of brentuximab prior to ASCT or as maintenance after ASCT will not be funded. As per the manufacturer's product monograph, the maximum dose that can be administered is based on a weight of 100kg.
Brentuximab (bren-tuk-see-mab) Other name: Adcertis®	Systemic Anaplastic Large Cell Lymphoma	Brentuximab will be used as monotherapy in patients with systemic anaplastic large cell lymphoma who have failed at least one prior multi-agent chemotherapy regimen and who have an ECOG performance status of 0 or 1.	Brentuximab 1.8 mg/kg IV every 3 weeks until disease progression or unacceptable toxicity.	A pathology report confirming CD30+ve systemic anaplastic large cell lymphoma and a clinic note outlining the patient's treatment history must be submitted to CCO prior to the start of treatment. Treatments beyond 16 cycles require documentation showing continued evidence of benefit (i.e., a clinic note and CT scan confirming that there is no evidence of disease progression). The documentation can be submitted with the treatment claims. Use of brentuximab in the first line setting or as a bridge to allogeneic stem cell transplant will not be funded. As per the manufacturer's product monograph, the maximum dose that can be administered is based on a weight of 100kg.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				Romidepsin funding is also available for patients with the CD30+ systemic anaplastic large cell lymphoma subtype of peripheral T-cell lymphoma, provided funding criteria are met. No evidence exists to inform the optimal sequencing for brentuximab or romidepsin. The choice in sequencing should be based on a discussion between the treating hematologist and patient.
Cabazitaxel (ca-BA-zee-tax-el) Other name: Jevtana™	Metastatic Castration – Resistant Prostate Cancer	Cabazitaxel will be used in combination with prednisone for the treatment of metastatic castrate – resistant prostate cancer (mCRPC) who have progressed on or within 12 months of completing docetaxel – containing therapy	Cabazitaxel 25 mg/m^2 IV every 3 weeks (with 10mg oral prednisone daily) until disease progression	Cabazitaxel is not funded if used: • in combination with abiraterone (Zytiga) or enzalutamide (Xtandi) for metastatic castrate-resistant prostate cancer; or • in patients who have failed (i.e., disease progression) abiraterone or enzalutamide for metastatic castrate-resistant prostate cancer in the post-docetaxel setting; or • as the first line treatment of metastatic castrate-resistant prostate cancer For patients currently on abiraterone or enzalutamide in the post-docetaxel setting, requests to switch over to cabazitaxel may be considered provided: (i) the above criteria are met, (ii) disease progression on abiraterone or enzalutamide has not yet occurred, and (iii) the patient initiated treatment with either abiraterone or enzalutamide within the past 3 months of making the request for cabazitaxel.
Cetuximab (se-TUX-i-mab) Other name: Erbitux®	Third Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer (with irinotecan)	a. The patient has metastatic colon, rectal, small bowel, or appendiceal cancer b. The patient has failed chemotherapy regimens containing oxaliplatin and irinotecan c. The tumour has non-mutated (wild-type) RAS oncogene d. Cetuximab will be used in combination with irinotecan as third line therapy	One of the following regimens for cetuximab: • Loading dose of 400 mg/m^2 IV, followed by weekly 250 mg/m^2 IV until disease progression, or • 500 mg/m^2 every 2 weeks (no loading dose) One of the following regimens for irinotecan: • 350 mg/m^2 IV every 3 weeks, or • 180 mg/m^2 every 2 weeks, or • 125 mg/m^2 on days 1, 8, 15 and 22 every 6 weeks	1. Treatments administered prior to RAS testing will not be reimbursed. 2. A copy of the RAS test result must be provided to the NDFP. 3. If the patient experiences intolerance to this regimen and the physician would like to use panitumumab, please submit a Prior Approval request for panitumumab in eClaims along with relevant documentation for review.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				4. Patients who previously received panitumumab in the first line setting are not eligible for subsequent treatment with cetuximab.
Cetuximab (se-TUX-i-mab) Other name: Erbitux®	Locally Advanced Squamous Cell Carcinoma of the Head and Neck (and radiation)	a. The patient has locally or regionally advanced squamous cell carcinoma of the head and neck without distant metastases b. The patient is unable to use cisplatin or carboplatin/5FU due to a medical contraindication (i.e., true platinum allergy or where the use of myelosuppressive drugs is contraindicated) c. Cetuximab is used concurrently with acceptable radiation schedules that plan to intensify the delivery of radiation, such as accelerated radiotherapy	Cetuximab 400 mg/m^2 IV loading dose, followed by 250 mg/m^2 IV weekly for 6 to 7 weeks Treatment is limited to the duration of radiation therapy	N/A
Clodronate (CLOE-dron-ate) Other names: Bonefos®, Ostac®, Clasteon®	Metastatic Breast Cancer	The patient must meet criteria a, b and one of c: a. The patient has metastatic breast cancer b. The patient has bone metastases c. The patient: • was given oral clodronate and is unable to tolerate it • is likely to be unable to tolerate oral clodronate (e.g. the patient is on IV chemotherapy or has pre-existing nausea related to medications or disease)	Maximum dose: clodronate 1500 mg every 3 to 4 weeks	N/A
Denosumab (den-OH-sue-mab) Other name: Xgeva®	Hormone Refractory Prostate Cancer	Denosumab will be used for the treatment of bony metastases for patients with hormone refractory prostate cancer as determined by an elevated PSA level, or evidence of progressive bony disease, despite castrate serum testosterone levels (<1.7 nmol/L or 50ng/dL)	Denosumab 120 mg SC every 4 weeks	Evidence of progressive bony disease can be demonstrated by progressive changes in radionucleotide bone scan or clinical signs of disease progression (e.g., pathologic fracture or increasing bone pain) Serum testosterone level does not apply for patients who have undergone orchidectomy
Docetaxel (doe-seh-TAX-ell) Other name: Taxotere®	Metastatic Castration-Resistant Prostate Cancer	a. Patient has metastatic castration-resistant prostate cancer (mCRPC is defined as rising PSA or progression of metastatic disease in the face of castrate testosterone levels.) b. Patient has metastases c. Patient is: • Symptomatic • Asymptomatic (Symptomatic status does not affect eligibility. This	Patient will receive docetaxel: 75 mg/m^2 IV q3 weeks with oral prednisone 5 mg twice daily. (Preferred regimen that has demonstrated overall survival, disease control, symptom palliation and quality of life benefit compared to mitoxantrone and prednisone.) OR, 30 mg/m^2 IV weekly for 5 out of every 6 weeks plus oral prednisone 5 mg twice daily. (This regimen is approved for patients who cannot tolerate the q3 week regimen or are presenting with pancytopenia.	N/A

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		information is being collected for future analysis.)	This regimen has demonstrated a quality of life benefit, but no survival benefit when compared to mitoxantrone and prednisone.)	
Docetaxel (doe-seh-TAX-ell) Other name: Taxotere®	Hormone Sensitive Prostate Cancer	For patients with metastatic castration sensitive prostate cancer who have visceral metastases and/or 4 or more bone metastases with at least one beyond pelvis and vertebral column	Docetaxel 75 mg/m^2 every 3 weeks up to a maximum of 6 cycles	N/A
Docetaxel (doe-seh-TAX-ell) Other name: Taxotere®	Adjuvant Treatment for Breast Cancer	Patient must meet one of the following criteria: • node positive breast cancer • high risk node negative breast cancer High risk features include: • Large tumour size (Specify) • High tumour grade (Specify) • Lymphovascular invasion • Estrogen receptor negative • Progesterone receptor negative • HER-2 neu positive • Age less than 40 • Other (Specify)	One of the following regimens: • Docetaxel as part of the FEC-T regimen (100 mg/m^2 per cycle x 3 cycles funded), or • Docetaxel as part of AC-Taxotere regimen (100 mg/m^2 per cycle x 4 cycles funded)	N/A
Docetaxel (doe-seh-TAX-ell) Other name: Taxotere®	Early Operable Breast Cancer	The patient must meet one of the following criteria: • The patient has node positive breast cancer or • node negative breast cancer	Docetaxel will be given as part of the TC regimen: • docetaxel 75 mg/m^2, and • cyclophosphamide 600 mg/m^2 every 21 days for 4 cycles (not funded by NDFP)	N/A
Docetaxel (doe-seh-TAX-ell) Other name: Taxotere®	Metastatic Breast Cancer	One of the following criteria must be met: a. The patient has metastatic breast cancer and will be treated first line with docetaxel b. The patient has metastatic breast cancer and will be treated first line with docetaxel in combination with doxorubicin c. The patient has metastatic breast cancer and will be treated with docetaxel and meets one of the following criteria: • cannot tolerate anthracyclines • has failed anthracycline therapy for metastatic disease • has received an anthracycline as adjuvant therapy	**No specified funded dose. For recommended dose, see CCO Drug Formulary**	The NDFP will fund only one of the 3 drugs (paclitaxel, docetaxel or vinorelbine) for any metastatic breast cancer patient. Nab-Paclitaxel may be used in place of paclitaxel or docetaxel provided that the patient meets nab-paclitaxel eligibility criteria.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Docetaxel (doe-seh-TAX-ell) Other name: Taxotere®	Neoadjuvant treatment for Non-Metastatic Breast Cancer	The patient must meet criteria a and one of b: a. The patient has non-metastatic breast cancer and will receive neoadjuvant chemotherapy b. The reason for using neoadjuvant treatment is: • the patient has inoperable, locally advanced disease • the patient has inflammatory breast cancer • to downsize the tumour to allow for breast conserving surgery	One of the following regimens: • Docetaxel as part of the FEC-T regimen (100 mg/m^2 per cycle x 3 cycles funded) • Docetaxel as part of AC-Taxotere regimen (100 mg/m^2 per cycle x 4 cycles funded)	N/A
Docetaxel (doe-seh-TAX-ell) Other name: Taxotere®	Non-Small Cell Lung Cancer (NSCLC)	Patient must meet criteria a and one of b a. The patient has locally advanced or metastatic non-small cell lung cancer. b. One of the following: • The drug will be administered as first line (or induction) treatment • The patient has received either EGFR- or ALK-targeted therapy as their initial treatment and a non-pemetrexed platinum doublet is used as the next line of chemotherapy option (induction) • The patient has experienced excessive toxicity with another first line agent for NSCLC doses and needs to be switched to a different first line drug	**No specified funded dose. For recommended dose, see CCO Drug Formulary**	The NDFP will fund **up to 6 cycles**, based on evidence that chemotherapy given for longer than 3 to 4 cycles is not associated with improvement in overall survival, but rather may lead to worsened toxicity and a possible worsening of quality of life.
Docetaxel (doe-seh-TAX-ell) Other name: Taxotere®	Non-Small Cell Lung Cancer (Second or Subsequent Line)	Docetaxel is used as monotherapy for the second (or subsequent) line of treatment of locally advanced or metastatic non-small cell lung cancer in patients who have disease progression following any treatment option.	75 mg/m^2 every 3 weeks	Patients who have previously used erlotinib are not eligible for docetaxel funding.
Epirubicin (e-pee-ROO-bi-sin) Other name: Pharmorubicin PFS®	Adjuvant Treatment for Breast Cancer	Patient has either: • node positive breast cancer • high risk node negative breast cancer High risk features include: • Large tumour size (Specify) • High tumour grade (Specify) • Lymphovascular invasion • Estrogen receptor negative • Progesterone receptor negative • HER-2 neu positive • Age less than 40 • Other (Specify)	One of the following, epirubicin as part of: • FEC-T regimen (100 mg/m^2 per cycle x 3 cycles funded), or • CEF • FEC-100 x 6 cycles • Other (specify)	N/A

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Epirubicin (e-pee-ROO-bi-sin) Other name: Pharmorubicin PFS®	Neoadjuvant treatment for Non – Metastatic Breast Cancer	The patient must meet criteria a and one of b: a. The patient has non-metastatic breast cancer and will receive neoadjuvant chemotherapy b. The reason for using neoadjuvant treatment is: • the patient has inoperable, locally advanced disease • the patient has inflammatory breast cancer • to downsize the tumour to allow for breast conserving surgery	One of the following, epirubicin as part of: • FEC-T regimen (100 mg/m^2 per cycle x 3 cycles funded), or • CEF • FEC-100 x 6 cycles • Other (specify)	N/A
Eribulin (ER-i-BUE-lin) Other name: Halaven®	Metastatic or Incurable Locally Advanced – Breast Cancer	**The patient meets all of the following criteria:** • Eribulin is used for the treatment of a patient with metastatic or incurable locally advanced breast cancer who has had previous treatment with a taxane and an anthracycline, whose disease has progressed following at least two chemotherapy regimens for metastatic or locally recurrent disease, and whose disease has progressed after the last therapy; and • The patient has good performance status (ECOG ≤ 2)	Eribulin 1.4 mg/m^2 IV on Days 1 and 8 of a 21 day cycle.	N/A
Fludarabine (flu-DA-ra-been) Other name: Fludara®	Indolent Lymphoma	a. The patient has stage III-IV follicular or other indolent B-cell histology lymphoma (e.g., mantle cell lymphoma, marginal zone lymphoma, lymphoplasmacytoid lymphoma [Waldenstrom's Macroglobulinemia], hairy cell leukemia, mucosa-associated lymphoid tissue [MALT] lymphoma but excluding diffuse small lymphocytic lymphoma/chronic lymphocytic leukemia.) b. The patient has experienced disease progression following first line therapy	**No specified funded dose. For recommended dose, see CCO Drug Formulary**	N/A
Gemcitabine (jem-SITE-a-been) Other name: Gemzar®	Carcinoma of Bladder or Urothelium	a. Patient has advanced unresectable or metastatic transitional cell carcinoma of the bladder or urothelium b. Patient has **no** medical contraindication to gemcitabine-cisplatin chemotherapy	Recommended dose: gemcitabine 1000 mg/m^2 on days 1, 8, 15 every 28 days	N/A
Gemcitabine (jem-SITE-a-been) Other name: Gemzar®	Non-Small Cell Lung Cancer (NSCLC)	Patient must meet criteria a and one of b: a. The patient has locally advanced or metastatic non-small cell lung cancer. b. One of the following: • The drug will be administered as first line (or induction) treatment • The patient has received either EGFR- or ALK-targeted therapy as their initial treatment and a non-	**No specified funded dose. For recommended dose, see CCO Drug Formulary**	The NDFP will fund up to 6 cycles, based on evidence that chemotherapy given for longer than 3 to 4 cycles is not associated with improvement in overall survival, but rather may lead to worsened toxicity and a possible worsening of quality of life.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		pemetrexed platinum doublet is used as the next line of chemotherapy option (induction) • The patient has experienced excessive toxicity with another first line agent for NSCLC doses and needs to be switched to a different first line drug		
Gemcitabine (jem-SITE-a-been) Other name: Gemzar®	Advanced Pancreatic Cancer	The patient has advanced pancreatic adenocarcinoma (locally advanced unresectable or metastatic pancreatic cancer) and is symptomatic and/or has measurable/evaluable disease.	Gemcitabine 1000 mg/m^2 weekly for 7 weeks followed by 1 week rest (cycle 1), then weekly for 3 out of every 4 weeks	To be used as a single agent only. Not reimbursed if given concurrently with radiation. Not reimbursed if used in the neoadjuvant or adjuvant setting (i.e. in surgically resectable pancreatic cancer). Upon progression, patient will **not** be eligible for the funding for the following NDFP advanced pancreatic cancer policies: • Gemcitabine/nab-paclitaxel regimen • Oxaliplatin and Irinotecan as part of the FOLFIRINOX regimen
Gemcitabine (jem-SITE-a-been) Other name: Gemzar®	Advanced Pancreatic Cancer (with Nab-Paclitaxel)	The patient must meet the following criteria: • The gemcitabine and nab-paclitaxel regimen will be used to treat first-line Advanced Pancreatic Cancer (Locally Advanced Unresectable Pancreatic Cancer or Metastatic Pancreatic Cancer) • Patient's ECOG is less than or equal to 2 at the time of enrolment	Gemcitabine 1000 mg/m^2 and nab-paclitaxel 125 mg/m^2 Days 1, 8, 15 every 28 days	Patients who are funded for this gemcitabine-nab-paclitaxel combination for the treatment of either locally advanced unresectable or metastatic pancreatic cancer will not be eligible for the funding of oxaliplatin and irinotecan under the FOLFIRINOX regimen and gemcitabine single agent. Nab-paclitaxel must be administered in combination with gemcitabine, and not as a single-agent Completion of this form will fulfill the enrolment requirements for both gemcitabine and nab-paclitaxel.
Interferon (in-ter-FEAR-on) Other name: Intron A®	Melanoma	a. The patient has melanoma b. The patient is one of the following: • at high risk for recurrence with depth of primary lesion = 4.00 mm, and/or • has regional nodal metastases that have been completely resected, and/or • The patient has cutaneous or subcutaneous metastases between the primary site and the regional lymph nodes (formally called satellite and in-transit	Maximum dose for reimbursement is 20x10^6 U/m^2 daily 5 days a week for 4 weeks	N/A

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		metastases) that have been completely surgically resected c. The patient has been made aware of the relative risks and benefits of interferon therapy d. Arrangements have been made for the funding of the ambulatory phase of the treatment **(Cancer Care Ontario does not fund this component of the treatment)**		
Ipilimumab (IP-i-LIM-ue-mab) Other name: Yervoy®	Previously Treated Advanced Unresectable Melanoma (Formerly Unresectable Stage III or IV Melanoma)	• **Initial Treatment:** Patient has unresectable Stage III or IV melanoma and has received at least one systemic therapy for advanced melanoma; the patient has an ECOG performance score ≤ 1; • **Re-induction:** At the time of disease progression, the patient has had stable disease for at least three months or has previously experienced a complete or partial response to ipilimumab; the patient has an ECOG performance score ≤ 1	Induction/Re-induction: Ipilimumab 3mg/kg every 3 weeks for 4 doses	1. Patients who have received ipilimumab before the effective funding date of pembrolizumab (i.e., received at least one treatment of ipilimumab prior to June 2, 2016) will be eligible to receive pembrolizumab upon disease progression. 2. Effective June 2, 2016, patients who have not received ipilimumab or pembrolizumab will be funded for pembrolizumab or ipilimumab, but not both. 3. Sequential use of ipilimumab after pembrolizumab (i.e., pembrolizumab first followed by ipilimumab) will not be publicly funded. 4. If patient has received ipilimumab funding in the firstline setting, he/she will not be eligible for ipilimumab funding for reinduction or in subsequent lines of therapy. 5. Ipilimumab is not funded if the patient has an ECOG ≥ 2.
Ipilimumab (IP-i-LIM-ue-mab) Other name: Yervoy®	Previously Untreated Advanced Unresectable Melanoma	• For the first-line treatment of patients who are at least 18 years old with advanced melanoma (i.e. primary cutaneous unresectable Stage IIIC or IV melanoma or metastatic melanoma), regardless of BRAF mutation status, who have an ECOG Performance Status less than or equal to 1, and are not currently receiving immunosuppressive therapy. • If a patient has brain metastasis, then he or she must be asymptomatic or stable.	Ipilimumab 3mg/kg every 3 weeks for 4 doses	1. Patients who have received ipilimumab before the effective funding date of pembrolizumab (i.e., received at least one treatment of ipilimumab prior to June 2, 2016) will be eligible to receive pembrolizumab upon disease progression. 2. Effective June 2, 2016, patients who have not received ipilimumab or pembrolizumab will be funded for pembrolizumab or ipilimumab, but not both. 3. Sequential use of ipilimumab after pembrolizumab (i.e., pembrolizumab first followed by ipilimumab) will not be publicly funded.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				4. If patient has received ipilimumab in the firstline setting, they will not be eligible for ipilimumab funding for reinduction or in subsequent lines of therapy (NDFP Policy: Previously Treated Advanced Unresectable Melanoma). 5. Requests for dose escalation up to 10 mg/kg will not be considered. 6. Maintenance or reinduction requests in the first line setting will not be considered.
Irinotecan (eye-reen-oh-TEE-can) Other name: Camptosar®	First Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer	a. The patient has metastatic colon, rectal, small bowel, or appendiceal cancer b. ECOG Performance Status is 0 – 2	One of the following regimens: • Irinotecan 180 mg/m^2 every 2 weeks, or • Irinotecan 125 mg/m^2 weekly x 4 every 6 weeks, or • Irinotecan 350 mg/m^2 every 3 weeks	NDFP only funds irinotecan if it is used in accordance with the evidence-informed regimens listed in the ST-QBP (https://www.cancercare.on.ca/toolbox/drugformulary/stfmregimens/).
Irinotecan (eye-reen-oh-TEE-can) Other name: Camptosar®	Second Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer	a. The patient has metastatic colon, rectal, small bowel, or appendiceal cancer b. The patient has not received prior treatment with irinotecan for metastatic disease c. The patient has failed treatment with a TS inhibitor (5FU+LV, raltitrexed, etc.) for metastatic disease d. ECOG Performance Status is 0 – 2	One of the following regimens: • Irinotecan 180 mg/m^2 every 2 weeks, or • Irinotecan 125 mg/m^2 weekly x 4 every 6 weeks, or • Irinotecan 350 mg/m^2 every 3 weeks	NDFP only funds irinotecan if it is used in accordance with the evidence-informed regimens listed in the ST-QBP (https://www.cancercare.on.ca/toolbox/drugformulary/stfmregimens/).
Irinotecan (eye-reen-oh-TEE-can) Other name: Camptosar®	Third Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer (with Cetuximab)	a. The patient has metastatic colon, rectal, small bowel, or appendiceal cancer b. The patient has failed chemotherapy regimens containing oxaliplatin and irinotecan c. The tumour has non-mutated (wild-type) RAS oncogene d. Cetuximab will be used in combination with irinotecan as third line therapy	One of the following regimens for irinotecan: • 350 mg/m^2 IV every 3 weeks, or • 180 mg/m^2 every 2 weeks, or • 125 mg/m^2 on days 1, 8, 15 and 22 every 6 weeks One of the following regimens for cetuximab: • Loading dose of 400 mg/m^2 IV, followed by weekly 250 mg/m^2 IV until disease progression, or • 500 mg/m^2 every 2 weeks (no loading dose)	1. Treatments administered prior to RAS testing will not be reimbursed. 2. A copy of the RAS test result must be provided to the NDFP. 3. If the patient experiences intolerance to this regimen and the physician would like to use panitumumab, please submit a Prior Approval request for panitumumab in eClaims along with relevant documentation for review. 4. Patients who previously received panitumumab in the first line setting are not eligible for subsequent treatment with cetuximab.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Irinotecan (eye-reen-oh-TEE-can) Other name: Camptosar®	Advanced Pancreatic Cancer (FOLFIRINOX with Oxaliplatin)	a. Oxaliplatin and irinotecan will be used as part of the FOLFIRINOX regimen for the first line treatment of Locally Advanced **Unresectable** Pancreatic Cancer or Metastatic Pancreatic Cancer b. The patient has an ECOG performance status of 0 to 1 and bilirubin < 1.5 upper limit of normal (ULN) (26 mmol/L)	Irinotecan 180 mg/m^2 IV Day 1 and Oxaliplatin 85 mg/m^2 IV Day 1, to be given every 2 weeks	Patients who are funded for FOLFIRINOX for the treatment of either locally advanced **unresectable** or metastatic pancreatic cancer will not be eligible for the funding of the gemcitabine/nab-paclitaxel combination, but will be eligible for single agent gemcitabine upon progression. Completion of this form will fulfill the enrolment requirements for both oxaliplatin and irinotecan. FOLFIRINOX will not be considered for funding if used for the treatment of neoadjuvant or adjuvant pancreatic cancer. Clinicians who offer FOLFIRINOX to their patients must be aware of the toxicities associated with this regimen in the context of the eligibility criteria from the French trial (N Engl J Med. 2011 May 12; 364(19):1817-25.), including the fact that accrual was limited to patients less than or equal to 75 years of age. Bolus 5FU may be omitted from the FOLFIRINOX regimen if there is concern over toxicity. Reported hematologic toxicities include: neutropenia, febrile neutropenia, thrombocytopenia, and anemia. Reported nonhematologic events include: fatigue, vomiting, diarrhea, sensory neuropathy, elevated level of alanine aminotransferase, thromboembolism.
Liposomal Doxorubicin (lip-o-SO-mal docs-oh-RUBE-i-sin) Other name: Caelyx®	Platinum – Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	a. Patient has previously been treated with platinum-containing chemotherapy: with Paclitaxel or without Paclitaxel (please specify) b. One of the following: • disease has relapsed less than 6 months following therapy • tumour has progressed during therapy or not responding to therapy c. Patient has reasonable performance status with symptoms that are likely to be alleviated if response is achieved	Liposomal doxorubicin 50 mg/m^2 every 4 weeks	Patients are eligible for treatment with either topotecan or liposomal doxorubicin. Patients having already received one of these drugs are not eligible to receive funding for the other.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Liposomal Doxorubicin (lip-o-SO-mal docs-oh-RUBE-i-sin) Other name: Caelyx®	Single Agent Treatment of Platinum Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer for Patients Unable to Receive Platinum Therapy	a. The patient: is platinum sensitive (Patients are considered platinum sensitive if they have had a response of 6 months or longer from the date of their last platinum containing therapy) or, has had a response of 6 months or longer from the date of the last single agent therapy b. The patient is not able to receive treatment with a platinum agent (e.g. allergy)	Liposomal Doxorubicin 50 mg/m^2 IV q28 days	Platinum sensitive patients are eligible to receive single agent paclitaxel and either liposomal doxorubicin or topotecan as a single agent.
Liposomal Doxorubicin (lip-o-SO-mal docs-oh-RUBE-i-sin) Other name: Caelyx®	HIV-positive Kaposi's Sarcoma	a. Patient has HIV-positive Kaposi's sarcoma b. Patient has either: • visceral Kaposi's sarcoma • progressive disease despite prior therapy with vinblastine or interferon c. Patient has either : • signs of peripheral neuropathy or is believed to be at high risk of neuropathy • other medical condition that makes it inappropriate to use standard combination chemotherapy. Please specify the nature of the condition d. ECOG performance status is 0-2	Liposomal doxorubicin 20 mg/m^2 every 2 weeks	N/A
Liposomal Doxorubicin (lip-o-SO-mal docs-oh-RUBE-i-sin) Other name: Caelyx®	Platinum-sensitive recurrent ovarian, fallopian tube, or primary peritoneal cancer (with carboplatin)	The patient must meet the following criteria: • Pegylated liposomal doxorubicin is used in combination with carboplatin for the treatment of platinum-sensitive recurrent ovarian, fallopian tube, or primary peritoneal cancer	Pegylated liposomal doxorubicin 30mg/m^2 IV on Day 1 every 4 weeks until disease progression or unacceptable toxicity. ST-QBP will fund carboplatin AUC 4-6 IV Day 1 every 4 weeks (regimen CRBPPGLDX).	1. Platinum-sensitive is defined as having a disease which recurs or progresses 6 months or longer from the date of the last dose of platinum-containing therapy. 2. Pegylated liposomal doxorubicin is only funded once (i.e., as one line of therapy, either as a single agent or as part of a combination regimen) for the treatment of recurrent ovarian, fallopian tube, or primary peritoneal cancer. 3. Retreatment with this regimen (or a pegylated liposomal doxorubicin-based regimen) is not funded by NDFP. 4. NDFP will fund one of pegylated liposomal doxorubicin or topotecan (but not both) for the treatment of recurrent ovarian, fallopian tube, or primary peritoneal cancer.
Nab-Paclitaxel (nab pack-li-TAX-ell) Other name: Abraxane®	Metastatic Breast Cancer	The patient must meet criteria a, b OR c, and d: a. The patient has metastatic breast cancer. b. Has had acute infusion reactions with paclitaxel or docetaxel considered by treating physicians to be due to the vehicle of the taxanes (Cremophor and polysorbate 80)	**No specified funded dose. For recommended dose, see CCO Drug Formulary**	[a]excludes glycemic effects of steroids The NDFP will fund only one of the 3 drugs (paclitaxel, docetaxel or vinorelbine) for any metastatic breast cancer patient. Nab-Paclitaxel may be used in place of paclitaxel

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		c. Has experienced severe toxicity from previous administration of other taxanes (Severe toxicity could be due to pre-medications for the administration of the taxane or due to the taxane itself)[a] d. Specify previous taxane: docetaxel or paclitaxel		or docetaxel provided that the patient meets nab-paclitaxel eligibility criteria.
Nab-Paclitaxel (nab pack-li-TAX-ell) Other name: Abraxane®	Advanced Pancreatic Cancer (with Gemcitabine)	The patient must meet the following criteria: • The gemcitabine and nab-paclitaxel regimen will be used to treat first-line Advanced Pancreatic Cancer (Locally Advanced **Unresectable** Pancreatic Cancer or Metastatic Pancreatic Cancer) • Patient's ECOG must be less than or equal to 2 at the time of enrolment	Gemcitabine 1000 mg/m^2 and nab-paclitaxel 125 mg/m^2 Days 1, 8, 15 every 28 days	Patients who are funded for this gemcitabine-nab-paclitaxel combination for the treatment of either locally advanced unresectable or metastatic pancreatic cancer will not be eligible for the funding of oxaliplatin and irinotecan under the FOLFIRINOX regimen and gemcitabine single agent. Nab-paclitaxel must be administered in combination with gemcitabine, and not as a single-agent Completion of this form will fulfill the enrolment requirements for both gemcitabine and nab-paclitaxel.
Nivolumab (nye-VOL-ue-mab) Other name: Opdivo®	Advanced Melanoma (Unresectable or Metastatic Melanoma)	The patient must meet the following criteria: • Nivolumab is used as a treatment for patients with unresectable or metastatic BRAF wild-type melanoma who are previously untreated, with good performance status and who have stable brain metastases (if present).	Nivolumab 3mg/kg IV every 2 weeks as an intravenous infusion	1. The patient is no longer eligible for nivolumab once there is confirmed disease progression. 2. Nivolumab is not funded for patients who have confirmed disease progression after receiving a prior anti-PD-1 inhibitor in the metastatic setting. 3. For patients treated with first line nivolumab, public funding will not be provided for subsequent treatments with ipilimumab. 4. Nivolumab funding is for single agent use only.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Nivolumab (nye-VOL-ue-mab) Other name: Opdivo®	Advanced or Metastatic Non-Small Cell Lung Cancer	The patient must meet the following criteria: • Nivolumab is used as a treatment for adult patients with advanced or metastatic non-small cell lung cancer (NSCLC) with disease progression on or after cytotoxic chemotherapy for advanced disease and who have a good performance status.	Nivolumab 3mg/kg IV every 2 weeks as an intravenous infusion	1. It is recommended that nivolumab be used after treatment with a platinum-based therapy. 2. The patient is no longer eligible for nivolumab once there is confirmed disease progression. 3. Nivolumab is not funded for patients who have confirmed disease progression after receiving a prior anti-PD-1 inhibitor in the metastatic setting. 4. Nivolumab funding is for single agent use only.
Nivolumab (nye-VOL-ue-mab) Other name: Opdivo®	Advanced or Metastatic Renal Cell Carcinoma and No Prior mTOR Inhibitor	The patient must meet the following criteria: • Nivolumab is used as a treatment for patients with advanced or metastatic renal cell carcinoma with disease progression after at least one prior anti-angiogenic systemic treatment and who have good performance status.	Nivolumab 3mg/kg IV every 2 weeks as an intravenous infusion	1. Nivolumab is funded as a second line treatment for patients that have received one prior tyrosine kinase inhibitor (e.g., first line sunitinib or pazopanib), OR as a third line treatment for patients that have received two prior tyrosine kinase inhibitors (e.g., first line sunitinib or pazopanib, second line axitinib). 2. Patients previously treated with an mTOR inhibitor (e.g., everolimus or temsirolimus), will not be eligible for coverage for nivolumab. However, patients previously treated with an mTOR inhibitor, prior to the public listing of nivolumab, will be eligible to receive coverage for nivolumab upon disease progression. 3. For patients treated with nivolumab, public funding will not be provided for subsequent drug therapies. 4. The patient is no longer eligible for nivolumab once there is confirmed disease progression. 5. Nivolumab is not funded for patients who have confirmed disease progression after receiving a prior anti-PD-1 inhibitor in the metastatic setting. 6. Nivolumab funding is for single agent use only.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Nivolumab (nye-VOL-ue-mab) Other name: Opdivo®	Advanced or Metastatic Renal Cell Carcinoma and Prior mTOR Inhibitor	The patient must meet the following criteria: • Nivolumab is used as a treatment for patients with advanced or metastatic renal cell carcinoma with disease progression after at least one prior anti-angiogenic systemic treatment and who have good performance status.	Nivolumab 3mg/kg IV every 2 weeks as an intravenous infusion	1. Nivolumab is funded as a second line treatment for patients that have received one prior tyrosine kinase inhibitor (e.g., first line sunitinib or pazopanib), OR as a third line treatment for patients that have received two prior tyrosine kinase inhibitors (e.g., first line sunitinib or pazopanib, second line axitinib). 2. Patients previously treated with an mTOR inhibitor (e.g., everolimus or temsirolimus), will not be eligible for coverage for nivolumab. However, patients previously treated with an mTOR inhibitor, prior to the public listing of nivolumab, will be eligible to receive coverage for nivolumab upon disease progression. 3. For patients treated with nivolumab, public funding will not be provided for subsequent drug therapies. 4. The patient is no longer eligible for nivolumab once there is confirmed disease progression. 5. Nivolumab is not funded for patients who have confirmed disease progression after receiving a prior anti-PD-1 inhibitor in the metastatic setting. 6. Nivolumab funding is for single agent use only.
Obinutuzumab (oh-bi-nue-tooz-ue-mab) Other name: Gazyva®	Previously Untreated Chronic Lymphocytic Leukemia	a. Patient has previously untreated chronic lymphocytic leukemia (CLL) b. Patient has adequate renal function c. Fludarabine-based treatment is considered inappropriate for this patient d. Obinutuzumab will be used in combination with chlorambucil	Cycle 1: 100 mg intravenously on day 1, 900 mg intravenously on day 2, 1000 mg intravenously on days 8 and 15. Cycles 2 to 6: 1000 mg intravenously on day 1 only. Cycles are 28 days. Obinutuzumab will be used in combination with chlorambucil.	1. On a time limited basis (6 months), patients who initiated chlorambucil for previously untreated CLL in the three months prior to July 17, 2015 and whose disease has not progressed will have the option of adding obinutuzumab. 2. To be eligible for funding, patients must be able to start obinutuzumab in combination with chlorambucil. During the course of treatment, chlorambucil may be temporarily held due to toxicity or intolerance. 3. Screening for Hepatitis B virus with HbsAg and HbcAb has been completed or is in progress

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Oxaliplatin (ox-AL-ih-plah-tin) Other name: Eloxatin®	Adjuvant Colorectal, Small Bowel, or Appendiceal Cancer	a. The patient has colon, rectal, small bowel or appendiceal cancer b. The patient has high-risk stage II disease or stage III disease c. The patient is receiving FOLFOX regimen, FLOX regimen, or XELOX/CAPOX regimen	Oxaliplatin is funded if used in FOLFOX, FLOX, or XELOX/CAPOX regimens. In FOLFOX, the cycle consists of oxaliplatin (85 mg/m^2 per cycle), leucovorin, a 5FU push and a 5FU CIV. All of these are given on Day 1 of the cycle and the CIV runs over 2 x 22 hours or 1 x 46 hours. The cycle is 14 days long and then repeats. Oxaliplatin is given 1 time in a cycle of FOLFOX, up to a maximum of 12 cycles. In FLOX, the cycle is 56 days long with oxaliplatin (85 mg/m^2 per cycle) given on Days, 1, 15 and 29, leucovorin and 5FU on Days 1, 8, 15, 22, 29 and 36. Thus oxaliplatin is given 3 times in a cycle of FLOX, up to a maximum of 3 cycles. In XELOX/CAPOX, the cycle is 21 days long with oxaliplatin (130 mg/m^2 per cycle) given IV on day 1 and capecitabine given orally days 1 to 14, up to a maximum of 8 cycles.	N/A
Oxaliplatin (ox-AL-ih-plah-tin) Other name: Eloxatin®	First Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer	a. The patient has metastatic colon, rectal, small bowel, or appendiceal cancer b. ECOG Performance Status is 0 – 2 c. The patient is at least 18 years of age d. The patient has adequate hematologic, hepatic, and renal function	One of the following regimens: FOLFOX regimens (using oxaliplatin doses of 85 mg/m^2 per cycle) until progression, or XELOX regimen (if coverage already exists for the capecitabine portion)	FOLFOX or XELOX may be used with or without bevacizumab for the <u>first line</u> treatment of metastatic colorectal, small bowel, or appendiceal cancer. **Oxaliplatin will not be reimbursed as a single agent.**
Oxaliplatin (ox-AL-ih-plah-tin) Other name: Eloxatin®	Second Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer	a. The patient has metastatic colon, rectal, small bowel, or appendiceal cancer b. ECOG Performance Status is 0 – 2 c. The patient is at least 18 years of age d. The patient has adequate hematologic, hepatic and renal function e. The patient has progressed: • on first line 5-FU or capecitabine monotherapy (TS inhibitor) and has a contraindication to second line irinotecan, or • following both irinotecan and a TS inhibitor	One of the following regimens: FOLFOX regimens (using oxaliplatin doses of 85 mg/m^2 per cycle) until progression, or XELOX regimen (if coverage already exists for the capecitabine portion)	**Oxaliplatin will not be reimbursed as a single agent.**

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Oxaliplatin (ox-AL-ih-plah-tin) Other name: Eloxatin®	With Surgery for Curative Intent for Colorectal, Small Bowel, or Appendiceal Cancer Patients with Resectable or Potentially Resectable Liver Metastases	Metastatic colorectal, small bowel, or appendiceal cancer patients deemed by a standards compliant multidisciplinary cancer conference (MCC) or equivalent[b], to have: Liver metastases that are resectable or potentially resectable[c]	Oxaliplatin used as part of FOLFOX (85 mg/m^2 per cycle, up to 12 cycles) in combination with surgery for curative intent. FOLFOX is given as one of the following: "pre-op", "post-op", or "perioperative (pre and post-op)"	a. The completed enrolment form along with documentation (e.g., a clinic note from the oncologist indicating that the patient's case has been discussed by a MCC or equivalent[b] including the MCC's recommendation) must be submitted to CCO. b. If outside an MCC setting, a collaborative discussion (by the medical and hepatobiliary surgical team, with the advice of appropriate pathology, radiology), must have occurred and been documented. c. ***"Resectable"*** refers to a patient who is deemed suitable for surgical resection at the time of MCC discussion. ***"Potentially resectable"*** refers to a patient whose disease is initially unresectable but is expected to be become resectable after use of downstaging chemotherapy. ***"Unresectable"*** refers to a patient with a large metastatic burden, or not medically fit, with a recommendation for standard palliative treatment (usually with chemotherapy). d. *Synchronous and metachronous* metastases may be considered. (Synchronous refers to metastases found at the time of resection of the primary tumour. Metachronous refers to metastases that occur more than 6 months after resection/treatment of the primary.) e. Eligible patients may have had or will have R0 (curative) resection of the primary cancer. f. If resection does not occur (or is unsuccessful), or if use of FOLFOX is unsuccessful, the patient may be transitioned over to the usual funded metastatic regimens. g. mCRC patients with "unresectable" liver metastases (as per MCC), whose disease becomes "resectable" after treatment with first line chemotherapy, are eligible to receive post-op FOLFOX. Upon disease progression, such patients will be eligible to receive the usual funded NDFP metastatic regimens. h. The funded NDFP regimen consists of oxaliplatin used as part of FOLFOX (85mg/m^2, up to 12 cycles). Chemotherapies outside of this setting will not be funded.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Oxaliplatin (ox-AL-ih-plah-tin) Other name: Eloxatin®	Advanced Pancreatic Cancer (FOLFIRINOX with irinotecan)	a. Oxaliplatin and irinotecan will be used as part of the FOLFIRINOX regimen for the first line treatment of Locally Advanced **Unresectable** Pancreatic Cancer or Metastatic Pancreatic Cancer b. The patient has an ECOG performance status of 0 to 1 and bilirubin < 1.5 upper limit of normal (ULN) (26 mmol/L)	Irinotecan 180 mg/m^2 IV Day 1 and Oxaliplatin 85 mg/m^2 IV Day 1, to be given every 2 weeks	Patients who are funded for FOLFIRINOX for the treatment of either locally advanced **unresectable** or metastatic pancreatic cancer will not be eligible for the funding of the gemcitabine/nab-paclitaxel combination, but will be eligible for single agent gemcitabine upon progression. Completion of this form will fulfill the enrolment requirements for both oxaliplatin and irinotecan. FOLFIRINOX will not be considered for funding if used for the treatment of neoadjuvant or adjuvant pancreatic cancer. Clinicians who offer FOLFIRINOX to their patients must be aware of the toxicities associated with this regimen in the context of the eligibility criteria from the French trial (N Engl J Med. 2011 May 12; 364(19):1817-25.), including the fact that accrual was limited to patients less than or equal to 75 years of age. Bolus 5FU may be omitted from the FOLFIRINOX regimen if there is concern over toxicity. Reported hematologic toxicities include: neutropenia, febrile neutropenia, thrombocytopenia, and anemia. Reported nonhematologic events include: fatigue, vomiting, diarrhea, sensory neuropathy, elevated level of alanine aminotransferase, thromboembolism.
Paclitaxel (pack-li-TAX-ell) Other name: Taxol®	Adjuvant Treatment for Breast Cancer	Patient has either: • node positive breast cancer • high risk node negative breast cancer High risk features include: Large tumour size (Specify), high tumour grade (specify), lymphovascular invasion, estrogen receptor negative, progesterone receptor negative, HER-2 neu positive, age less than 40, Other (Specify)	One of the following regimens: • Paclitaxel as part of AC-Paclitaxel (175 mg/m^2 q3 weeks x 4 treatments), or • Paclitaxel as part of AC-Paclitaxel dose dense (175 mg/m^2 q2 weeks x 4 treatments) with filgrastim or pegfilgrastim, or • Paclitaxel as part of AC-Paclitaxel weekly (80 mg/m^2 q1 weeks x 12 treatments). **Note: only up to 700 mg/m^2 will be funded (9 treatments)**	If using EC-Paclitaxel in the adjuvant setting, epirubicin is funded, but paclitaxel is not funded. Filgrastim and pegfilgrastim are not funded through NDFP.
Paclitaxel (pack-li-TAX-ell) Other name: Taxol®	Metastatic Breast Cancer	One of the following criteria: a. The patient has metastatic breast cancer and will be treated first line with paclitaxel in combination with doxorubicin	**No specified funded dose. For recommended dose, see CCO Drug Formulary**	The NDFP will fund only one of the 3 drugs (paclitaxel, docetaxel or vinorelbine) for any metastatic breast cancer patient. Nab-Paclitaxel may be used in place of paclitaxel

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		b. The patient has metastatic breast cancer and will be treated with paclitaxel and meets one of the following criteria: • cannot tolerate anthracyclines • has failed anthracycline therapy for metastatic disease • has received an anthracycline as adjuvant therapy		or docetaxel provided that the patient meets nab-paclitaxel eligibility criteria.
Paclitaxel (pack-li-TAX-ell) Other name: Taxol®	Neoadjuvant treatment for Non-Metastatic Breast Cancer	The patient must meet criteria a and one of b: a. The patient has non-metastatic breast cancer and will receive neoadjuvant chemotherapy b. The reason for using neoadjuvant treatment is: • the patient has inoperable, locally advanced disease • the patient has inflammatory breast cancer • to downsize the tumour to allow for breast conserving surgery	Paclitaxel as part of the AC-Paclitaxel regimen (up to 700 mg/m^2): • Paclitaxel as part of the AC-Paclitaxel regimen (175 mg/m^2 q3 weeks x 4 treatments), or • Paclitaxel as part of the AC-Paclitaxel dose dense regimen (175 mg/m^2 q2 weeks x 4 treatments) with filgrastim or pegfilgrastim, or • Paclitaxel as part of the AC-Paclitaxel weekly regimen (80 mg/m^2 q1 week x 12 treatments). **Note: only up to 700 mg/m^2 will be funded (9 treatments)**	If using EC-Paclitaxel in the neo-adjuvant setting, epirubicin is funded, but paclitaxel is not funded. Filgrastim and pegfilgrastim are not funded through NDFP.
Paclitaxel (pack-li-TAX-ell) Other name: Taxol®	First Line or Recurrent – Advanced Ovarian Carcinoma	The patient has: • stage II ovarian cancer • stage III or IV ovarian cancer optimally debulked (<1cm) • stage III or IV ovarian cancer sub optimally debulked (>1cm)	One of the following regimens: • 175 mg/m^2 every 3 weeks up to 9 treatments, or • weekly up to 27 treatments	Patients achieving a response of 6 months or longer from the date of their last dose of platinum-containing therapy (platinum-sensitive) are eligible for retreatment with a paclitaxel/platinum combination. This is still considered first-line therapy but patients must be enrolled in the Recurrent form.
Paclitaxel (pack-li-TAX-ell) Other name: Taxol®	First Line or Recurrent – Fallopian Tube Cancer	• The patient has fallopian tube cancer	One of the following regimens: • 175 mg/m^2 every 3 weeks up to 9 treatments, or • weekly up to 27 treatments	Patients achieving a response of 6 months or longer from the date of their last dose of platinum-containing therapy (platinum-sensitive) are eligible for retreatment with a paclitaxel/platinum combination. This is still considered first-line therapy but patients must be enrolled in the Recurrent form.
Paclitaxel (pack-li-TAX-ell) Other name: Taxol®	First Line or Recurrent – Primary Peritoneal Cancer	• The patient has primary peritoneal cancer	One of the following regimens: • 175 mg/m^2 every 3 weeks up to 9 treatments, or • weekly up to 27 treatments	Patients achieving a response of 6 months or longer from the date of their last dose of platinum-containing therapy (platinum-sensitive) are eligible for retreatment with a paclitaxel/platinum combination. This is still considered first-line therapy but patients must be enrolled in the Recurrent form.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Paclitaxel (pack-li-TAX-ell) Other name: Taxol®	First Line or Recurrent – Uterine Papillary Serous Carcinoma (UPSC)	• Patient has advanced uterine papillary serous carcinoma	One of the following regimens: • 175 mg/m^2 every 3 weeks up to 9 treatments, or • weekly up to 27 treatments	Patients achieving a response of 6 months or longer from the date of their last dose of platinum-containing therapy (platinum-sensitive) are eligible for retreatment with a paclitaxel/platinum combination. This is still considered first-line therapy but patients must be enrolled in the Recurrent form.
Paclitaxel (pack-li-TAX-ell) Other name: Taxol®	Non-Small Cell Lung Cancer (NSCLC)	Patient must meet criteria a and b a. The patient has locally advanced or metastatic non-small cell lung b. One of the following: • The drug will be administered as first line treatment • The patient is EGFR mutation positive and the disease has progressed following treatment with first line gefitinib • The patient has experienced excessive toxicity with another first line agent for NSCLC within the first 2 treatment doses and needs to be switched to a different first line drug	**No specified funded dose. For recommended dose, see CCO Drug Formulary**	1. The NDFP will fund **up to 6 cycles**, based on evidence that chemotherapy given for longer than 3 to 4 cycles is not associated with improvement in overall survival, but rather may lead to worsened toxicity and a possible worsening of quality of life 2. Funding for weekly paclitaxel with a platinum agent may be considered for patients with neuropathy, since there is no evidence of equivalent survival benefit when compared to q3 week paclitaxel/platinum, though there is suggestion of less neuropathy
Paclitaxel (pack-li-TAX-ell) Other name: Taxol®	Single Agent Treatment of Platinum Sensitive Ovarian, Fallopian Tube or Primary Peritoneal Cancer for Patients Unable to Receive Platinum Therapy	a. The patient: • is platinum sensitive (Patients are considered platinum sensitive if they have had a response of 6 months or longer from the date of their last platinum containing therapy.) • has had a response of 6 months or longer from the date of the last single agent therapy b. The patient is not able to receive treatment with a platinum agent (e.g. allergy)	Paclitaxel 175 mg/m^2 IV q21 days	Platinum sensitive patients are eligible to receive single agent paclitaxel and once they relapse are eligible for funding for **only one of** liposomal doxorubicin or topotecan as a single agent.
Pamidronate (pam-ID-droe-nate) Other name: Aredia®	Metastatic Breast Cancer	The patient must meet criteria a, b and one of c: a. The patient has metastatic breast cancer b. The patient has bone metastases c. The patient: • was given oral clodronate and is unable to tolerate it	Pamidronate 90 mg every 4 weeks, or Pamidronate (60-90 mg) every 3 weeks with scheduled chemotherapy	N/A

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		• is likely to be unable to tolerate oral clodronate (e.g. the patient is on IV chemotherapy or has pre-existing nausea related to medications or disease)		
Pamidronate (pam-ID-droe-nate) Other name: Aredia®	Plasma Cell Myeloma (with or without Bone Disease)	a. The patient has plasma cell myeloma b. One of the following: • The patient has no evidence of bone disease • The patient has evidence of bony lesions (lytic lesions or osteopenia)	90 mg IV q4 weeks	It is recommended that patients be treated for a minimum of 2 years. After 2 years of bisphosphonate treatment: • Patients who have achieved remission and are in stable plateau phase off treatment should consider discontinuing the use of bisphosphonates • Patients who still require active treatment for their myeloma should continue on bisphosphonates, but may consider having the frequency decreased to every 3 months if on pamidronate Patients whose myeloma becomes active following an initial response should resume monthly bisphosphonate therapy while on active treatment.
Panitumumab (PAN-i-TOOM-ue-mab) Other name: Vectibix®	In Combination with Chemotherapy for First Line Metastatic Colorectal, Small Bowel, or Appendiceal Cancer	The patient must meet the following criteria: • Panitumumab is used in addition to combination chemotherapy for the treatment of patients with wild-type RAS metastatic colorectal, small bowel, or appendiceal cancer in the first line treatment setting who have a contraindication or intolerance to bevacizumab and who would otherwise be treated only with combination chemotherapy. • Patients should have good performance status.	6 mg/kg every 2 weeks in combination with FOLFOX or FOLFIRI (ST-QBP regimen codes: MFOLFOX6+PNTM or FOLFIRI+PNTM). Note: a separate enrolment form is required for oxaliplatin as part of FOLFOX (Oxaliplatin – First Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer) or irinotecan as part of FOLFIRI (Irinotecan – First Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer). Treatment is funded until disease progression or unacceptable toxicity.	1. Examples of contraindications or intolerance to bevacizumab include: • High risk of bleeding or wound healing issues due to temporal proximity to surgery – recently received or planned for resectable/potentially resectable liver metastases. • A history of cardiovascular disease, or established class-specific side effects to bevacizumab such as hypertension, thromboembolic events, atrial fibrillation, as well as, proteinuria, risk of or presence of fistulae, risk of or current GI perforation, primary tumour in place, active bleeding, non-healing wound, ulcer, recent trauma, etc. 2. Treatments administered prior to RAS testing will not be reimbursed.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				3. Patients who use panitumumab in the first line setting will not be eligible for bevacizumab, cetuximab, or panitumumab in later lines of therapy. 4. Switches between bevacizumab and panitumumab will only be considered within the first 3 months of starting therapy with either agent, provided there is no disease progression on treatment. Patients will only be approved for one switch (i.e., from bevacizumab to panitumumab or vice versa). Please upload a clinic note indicating the reason(s) for switching and contraindication(s) to bevacizumab. 5. Panitumumab must be used in addition to combination chemotherapy. Single agent treatments will not be funded in the first line setting.
Panitumumab (PAN-i-TOOM-ue-mab) Other name: Vectibix®	Metastatic Colorectal, Small Bowel, or Appendiceal Cancer	a. The patient has metastatic colon, rectal, small bowel, or appendiceal cancer b. The patient has failed chemotherapy regimens containing oxaliplatin and irinotecan c. The tumour has non-mutated (wild-type) RAS oncogene d. The patient will be treated with single agent panitumumab	6 mg/kg every 2 weeks until disease progression	1. Treatments administered prior to RAS testing will not be reimbursed. 2. A copy of the RAS test result must be provided to Cancer Care Ontario. 3. Panitumumab will only be funded if given as a single agent. 4. Patients who previously received panitumumab in the first line setting are not eligible for subsequent treatment with panitumumab.
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	Pembrolizumab – Advanced Melanoma (Unresectable or Metastatic Melanoma) and no prior ipilimumab	The patient must meet the following criteria: • Pembrolizumab is used for the treatment of patients with advanced melanoma (unresectable or metastatic melanoma). • Patients are naïve to ipilimumab treatment (patients with BRAF mutation positive may or may not have received BRAF targeted therapy). • Treatment should be for patients with an ECOG performance status of 0 or 1, and who have stable brain metastases (if present).	Pembrolizumab 2mg/kg given once every 3 weeks as an intravenous infusion.	1. Patients who have received ipilimumab before the effective funding date of pembrolizumab (i.e., received at least one treatment of ipilimumab prior to June 2, 2016) will be eligible to receive pembrolizumab upon disease progression. Starting June 2, 2016, patients who have not received ipilimumab or pembrolizumab will be funded for pembrolizumab or ipilimumab, but not both. 2. Sequential use of ipilimumab (i.e., pembrolizumab first followed by ipilimumab) will not be publicly funded.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				3. Pembrolizumab funding is for 24 months or until disease progression, whichever occurs first. 4. Pembrolizumab funding is for single agent use only.
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	Pembrolizumab – Advanced Melanoma (Unresectable or Metastatic Melanoma) and prior ipilimumab	The patient must meet the following criteria: • Pembrolizumab is used in the treatment of patients with advanced melanoma (unresectable or metastatic melanoma). • Patients have failed ipilimumab, and if BRAF mutation positive, have also failed BRAF mutation therapy. • Treatment should be for patients with an ECOG performance status of 0 or 1, and who have stable brain metastases (if present).	Pembrolizumab 2mg/kg given once every 3 weeks as an intravenous infusion.	1. Patients who have received ipilimumab before the effective funding date of pembrolizumab (i.e., received at least one treatment of ipilimumab prior to June 2, 2016) will be eligible to receive pembrolizumab upon disease progression. Starting June 2, 2016, patients who have not received ipilimumab or pembrolizumab will be funded for pembrolizumab or ipilimumab, but not both. 2. Sequential use of ipilimumab (i.e., pembrolizumab first followed by ipilimumab) will not be publicly funded. 3. Pembrolizumab funding is for 24 months or until disease progression, whichever occurs first. 4. Pembrolizumab funding is for single agent use only.
Pemetrexed (peh-meh-TREX-edd) Other name: Alimta®	Advanced Malignant Pleural Mesothelioma (MPM)	Pemetrexed is used in combination with cisplatin for the first line treatment of advanced symptomatic malignant pleural mesothelioma and the patient is not suitable for surgical resection.	Pemetrexed 500 mg/m^2 and cisplatin 75 mg/m^2 on Day 1, repeated every 21 days until disease progression Cisplatin is not funded by NDFP.	Any modifications to the regimen require prior approval. Vitamin supplementation is mandatory starting at least 1 week prior to the first dose of pemetrexed and continuing until 3 weeks after the last dose of pemetrexed: • Vitamin B12: 1000 mcg IM every 9 week • Folic acid 0.4 – 1 mg PO daily Funding of pemetrexed will be discontinued if there is evidence of disease progression
Pemetrexed (peh-meh-TREX-edd) Other name: Alimta®	Combination with Platinum for Non-Small Cell Lung Cancer	The patient must meet <u>one</u> the following criteria: • Pemetrexed is used in combination with platinum for 4 to 6 cycles, for the first line (or induction) treatment of locally advanced or metastatic non-squamous non-small cell lung cancer. • The patient has received either EGFR- or ALK-targeted therapy as their initial treatment. Pemetrexed is used in combination with platinum for 4 to 6 cycles as a next line chemotherapy option (induction) for the	500 mg/m^2 on day 1 – repeat every 21 days for 4 to 6 cycles	Patients whose disease has progressed following treatment with pemetrexed (maintenance and/or prior lines of therapy) are not eligible for pemetrexed funding in the second or subsequent line setting. Funding of pemetrexed will be discontinued if there is evidence of disease progression. Patients who are continuing pemetrexed as a single agent (maintenance) after 4 to 6 cycles of pemetrexed-platinum should be enrolled under the policy 'Pemetrexed – Maintenance Treatment of Nonsquamous Non-Small Cell Lung Cancer'

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		treatment of locally advanced or metastatic non-squamous non-small cell lung cancer.		Vitamin supplementation is mandatory starting at least 1 week prior to the first dose of pemetrexed and continuing until 3 weeks after the last dose of pemetrexed: • Vitamin B 1000 mcg IM every 9 weeks • Folic acid 0.4 – 1 mg PO daily
Pemetrexed (peh-meh-TREX-edd) Other name: Alimta®	Maintenance Treatment of Nonsquamous Non-Small Cell Lung Cancer (NSCLC)	• Pemetrexed will be given as monotherapy for the maintenance treatment of locally advanced or metastatic nonsquamous non-small cell lung cancer following 4 to 6 cycles of platinum doublet induction treatment, which may include pemetrexed, for patients who achieved stable disease or better and who have an ECOG performance status of 0 or 1. • Maintenance therapy must be initiated within 42 days of the completion of 4 to 6 cycles of doublet therapy, and no disease progression has been noted.	500 mg/m^2 on day 1 – repeat every 21 days until disease progression.	Patients whose disease has progressed following treatment with pemetrexed (maintenance and/or prior lines of therapy) are not eligible for pemetrexed funding in the second or subsequent line setting. Funding of pemetrexed will be discontinued if there is evidence of disease progression. Vitamin supplementation is mandatory starting at least 1 week prior to the first dose of pemetrexed and continuing until 3 weeks after the last dose of pemetrexed: • Vitamin B_{12} 1000 mcg IM every 9 weeks • ii. Folic acid 0.4 – 1 mg PO daily
Pemetrexed (peh-meh-TREX-edd) Other name: Alimta®	Non-Small Cell Lung Cancer (following Crizotinib)	Pemetrexed is used as monotherapy for the third line treatment of a patient with ALK-positive locally advanced or metastatic nonsquamous non-small cell lung cancer whose disease has failed prior first line non-pemetrexed chemotherapy and second line crizotinib therapy and who has not received pemetrexed in an earlier line of therapy.	500 mg/m^2 on day 1 – repeat every 21 days until disease progression.	Patients whose disease has progressed following treatment with pemetrexed (maintenance and/or prior lines of therapy) are not eligible for pemetrexed funding in the second or subsequent line setting. Funding of pemetrexed will be discontinued if there is evidence of disease progression. Vitamin supplementation is mandatory starting at least 1 week prior to the first dose of pemetrexed and continuing until 3 weeks after the last dose of pemetrexed: • Vitamin B_{12} 1000 mcg IM every 9 weeks • ii. Folic acid 0.4 – 1 mg PO daily
Pemetrexed (peh-meh-TREX-edd) Other name: Alimta®	Non-Small Cell Lung Cancer (Second or Subsequent Line)	Pemetrexed is used as monotherapy for the second (or subsequent) line of treatment of locally advanced or metastatic nonsquamous non-small cell lung cancer in patients who have disease progression following any non-pemetrexed treatment option.	500 mg/m^2 on day 1 – repeat every 21 days until disease progression.	Patients whose disease has progressed following treatment with pemetrexed (maintenance and/or prior lines of therapy) are not eligible for pemetrexed funding in the second or subsequent line setting. Funding of pemetrexed will be discontinued if there is evidence of disease progression. Vitamin supplementation is mandatory starting at least 1 week prior to the first dose of pemetrexed and continuing until 3 weeks after the last dose of pemetrexed: • Vitamin B_{12} 1000 mcg IM every 9 weeks • ii. Folic acid 0.4 – 1 mg PO daily

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Pertuzumab (per-TOO-zoo-mab) Other names: Perjeta®	In combination with trastuzumab-taxane for HER2 positive unresectable locally recurrent or metastatic cancer	For use in combination with a taxane for the treatment of patients with HER2 positive unresectable locally recurrent or metastatic breast cancer with an ECOG status of 0 or 1, who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.	Loading dose of pertuzumab 840 mg and trastuzumab 8 mg/kg, followed every 3 weeks thereafter by a dose pertuzumab 420 mg and trastuzumab 6 mg/kg, until disease progression or unmanageable toxicity.	HER2 positive tumour status is confirmed either by IHC (score of 3+) and/or FISH/SISH/ISH (ratio of ≥ 2). A copy of the complete surgical pathology report must be provided to CCO. The results of the FISH/SISH/ISH test must also be provided if the IHC test result is equivocal. The patient must have a baseline left ventricular ejection fraction (LVEF) of ≥ 50% (as determined by a MUGA scan or ECHO). It is recommended that a MUGA scan or ECHO be repeated every 3 months during treatment to ensure that the LVEF is within the institution's normal limits. Pertuzumab is funded when given in combination with trastuzumab and a taxane. If the taxane is discontinued (e.g., after 6-8 cycles or due to unmanageable toxicity), continued treatment with pertuzumab-trastuzumab will be funded provided there is no evidence of disease progression while on treatment. If the time between two sequential infusions is 6 weeks or more, re-load with an initial dose of 840 mg pertuzumab and 8 mg/kg trastuzumab, followed every 3 weeks thereafter by a dose of 420 mg pertuzumab and 6 mg/kg trastuzumab.
Plerixafor (pleh-RIKS-ah-for) Other name: Mozobil®	Stem Cell Mobilization in non-Hodgkin's Lymphoma or Multiple Myeloma	a) Non-Hodgkin's Lymphoma, or b) Multiple Myeloma Plerixafor will be used in combination with filgrastim to mobilize hematopoietic stem cells for subsequent autologous transplantation; AND One of the following: a) The patient has a PBCD34+ count of less than 10 cells/µL after 4 days of filgrastim; OR b) Less than 50% of the target CD34 yield is achieved on the first day of apheresis (after being mobilized by filgrastim alone or following chemotherapy); OR c) If a patient has failed a previous stem cell mobilization with filgrastim alone or following chemotherapy	Plerixafor 0.24 mg/kg sc is given daily for a single mobilization attempt (maximum of 4 doses). The daily dose must not exceed 40 mg.	No Supporting documentation required for this policy. In the absence of collecting supporting documentation: • CCO reserves the right to perform an audit on the patient's eligibility to receive reimbursement for this policy • In the event of an audit, CCO may request a clinic note demonstrating: • Peripheral blood CD34+ count of less than 10 cells/ µL after 4 days of filgrastim (e.g., a clinic note and flow cytometry report); OR • Less than 50% of the target CD34 yield is achieved on the first day of apheresis (after being mobilized with filgrastim alone or chemotherapy, (e.g., a clinic note and flow cytometry report.) Please specify the drug(s) used in the previous attempt and indicate the target CD34 yield; OR • A clinic note documenting failure of a previous attempt at stem cell mobilization with filgrastim alone

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				or following chemotherapy. The drug(s) used in the previous attempt must be specified. CCO reserves the right to recover the cost of treatment calims if the requested documentation is not provided.
Porfimer Sodium – Photodynamic Therapy (POR-fimm-er) Other name: Photofrin®	Advanced non-small cell lung cancer	a. The patient has advanced non-small cell lung cancer b. The patient has symptomatic bronchial obstruction	Porfimer sodium 2 mg/kg IV	N/A
Radium-223 Dichloride (REY-dee-um DYE-klor-ide) Other name: Xofigo®	Castration-Resistant Prostate Cancer	Patient has castration-resistant prostate cancer (CRPC) with symptomatic bone metastases and no known visceral metastatic disease	**Effective until April 17, 2016:** Administered pre- or post-docetaxel, funded dose regimen is 50 kBq (1.35 microcurie) per kg body weight, given at 4 week intervals for a total of 6 injections. **Effective as of April 18, 2016:** Administered pre- or post-docetaxel, funded dose regimen is 55 kBq (1.49 microcurie) per kg body weight, given at 4 week intervals for a total of 6 injections. **If used in the pre-docetaxel setting, no subsequent funding will be considered in the post-docetaxel setting (NDFP policy: Docetaxel – Metastatic Castration-Resistant Prostate Cancer**	Please check the following to confirm and acknowledge that: • A consult with a medical or radiation oncologist has been done before starting radium • This enrolment will not be combined with cabazitaxel or enzalutamide or abiraterone for mCRPC • If radium is funded in the pre-docetaxel setting, no subsequent funding will be considered in the post-docetaxel setting
Raltitrexed (rall-tee-TREX-edd) Other name: Tomudex®	Advanced Malignant Pleural Mesothelioma (MPM)	a. The patient has advanced, symptomatic MPM b. The patient has good performance status (ECOG 0-1) c. The patient is not suitable for surgical resection	Raltitrexed 3 mg/m^2 IV combined with cisplatin 80 mg/m^2 IV on day 1 q3 weeks until disease progression Cisplatin is not funded by NDFP.	N/A
Raltitrexed (rall-tee-TREX-edd) Other name: Tomudex®	Metastatic Colorectal, Small Bowel, or Appendiceal Cancer	The patient must meet criteria a and one of b: a. The patient has metastatic colon, rectal, small bowel, or appendiceal cancer b. The patient: • Has experienced unacceptable toxicity with 5FU chemotherapy	Single agent raltitrexed 3 mg/m^2 every 21 days until evidence of disease progression or unacceptable toxicity	N/A

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		• Lives more than 60 km from the treatment centre/hospital • Has special transportation needs (i.e. ambulance or special vehicle for handicapped)		
Ramucirumab (RA-mue-SIR-ue-mab) Other name: Cyramza®	Advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma	The patient must meet the following criteria: a. Ramucirumab is used in combination with paclitaxel for the treatment of advanced or metastatic gastric cancer or gastro-esophageal junction (GEJ) adenocarcinoma with disease progression following first-line chemotherapy. b. Treatment should be for patients with an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.	Ramucirumab 8 mg/kg IV on days 1, 15 every 28 days until disease progression (to be used in combination with paclitaxel).	• To be eligible for funding, patients must be able to start ramucirumab in combination with paclitaxel. Paclitaxel may be temporarily held due to toxicity or intolerance. • In the event that a patient has to discontinue paclitaxel due to toxicity or intolerance, ramucirumab will continue to be funded. Relevant documentation (e.g., clinic note) is required. If disease progresses while on single agent ramucirumab, further funding of ramucirumab will be discontinued. • The paclitaxel component (i.e., paclitaxel IV on days 1, 8, and 15) of this regimen is funded through the Systemic Treatment Quality-Based Program (ST-QBP). The regimen is evidence-informed in the palliative setting and is known by regimen code PACL(W)+RAMU. ST-QBP funds the drug cost and the delivery cost of paclitaxel plus the delivery cost of ramucirumab. NDFP funds the drug cost of ramucirumab provided the patient meets the eligibility criteria. There is no NDFP enrolment form for paclitaxel for this indication.
Rituximab (rit-TUCKS-ee-mab) Other name: Rituxan®	Aggressive Histology Lymphoma	The patient must meet criteria a, b, and c: a. Patient has aggressive histology lymphoma – diffuse large B-cell lymphoma (DLBCL) or a variant of DLBCL (e.g., mediastinal sclerosing B-cell lymphoma, T-cell rich B-cell lymphoma, Burkitt-like lymphoma, intravascular lymphoma) b. Patient has <u>not</u> received previous treatment for aggressive histology lymphoma c. Patient is <u>not</u> known to be seropositive for HIV	Rituximab 375 mg/m^2 on day one of a standard CHOP (or CHOP-like) regimen for 6 to 8 cycles	Patients previously treated with rituximab for indolent histology lymphoma are eligible if the interval from the last dose of rituximab is greater than 1 year, provided a copy of the pathology report is submitted. Screening for Hepatitis B virus with HbsAg and HbcAb has been completed or is in progress.
Rituximab (rit-TUCKS-ee-mab) Other name: Rituxan®	HIV-Related, Aggressive Histology B-Cell Lymphoma	The patient has HIV-related, aggressive, CD20+ve B-cell lymphoma with CD4 counts that are greater than 50/mm^3 and has not received previous treatment for aggressive histology lymphoma	Rituximab 375 mg/m^2 on Day 1 of a standard CHOP, CHOP-like, or similar dose intense regimens for 6 to 8 cycles	The funded regimen consists of rituximab (375mg/m^2 per cycle), to be used with CHOP, CHOP-like, or similar dose intense regimens. Regimens outside of this setting will not be funded.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				Screening for Hepatitis B virus with HbsAg and HbcAb has been completed or is in progress.
Rituximab (rit-TUCKS-ee-mab) Other name: Rituxan®	Maintenance Treatment – Lymphoma	The patient must meet criteria a, b, c, and d: a. Patient has follicular lymphoma or other indolent B-cell histology lymphoma (e.g., mantle cell lymphoma, marginal zone lymphoma, lymphoplasmacytoid lymphoma (Waldenstrom's macroglobulinemia), hairy cell leukemia, mucosa-associated lymphoid tissue (MALT) lymphoma but excluding diffuse small lymphocytic lymphoma/ chronic lymphocytic leukemia) b. Patient has received and responded to induction therapy with one of the following: • Rituximab in combination with chemotherapy • Rituximab alone • Chemotherapy alone c. Patient was rituximab naïve prior to induction therapy for indolent histology lymphoma d. Maintenance rituximab will be initiated within 6 months of the last dose of induction therapy	Rituximab 375 mg/m^2 for a maximum of 8 doses over a 2 year period	Patients who present with concurrent aggressive and indolent histology lymphomas and are treated with rituximab induction therapy are eligible if maintenance rituximab is initiated within 6 months of the last dose of induction therapy. Please provide a copy of the pathology report. Screening for Hepatitis B virus with HbsAg and HbcAb has been completed or is in progress.
Rituximab (rit-TUCKS-ee-mab) Other name: Rituxan®	Previously Untreated Chronic Lymphocytic Leukemia	The patient must meet criterion a: a. Patient has previously untreated chronic lymphocytic leukemia where fludarabine-based therapy is considered appropriate	Cycle 1 – rituximab 375 mg/m^2 Cycles 2 through 6 – rituximab 500 mg/m^2	For patients with high tumour load, consider a slower infusion rate or split dosing over 2 days during the first cycle. Rituximab must be used with fludarabine-based chemotherapy. Patients on current fludarabine-based therapy may receive rituximab provided they have not progressed on therapy. Screening for Hepatitis B virus with HbsAg and HbcAb has been completed or is in progress.
Rituximab (rit-TUCKS-ee-mab) Other name: Rituxan®	Retreatment – Indolent Lymphoma	The patient must meet criteria a and b: a. Rituximab will be used in combination with chemotherapy for the treatment of follicular or other indolent lymphoma b. The patient has previously received rituximab (including combination rituximab-chemotherapy, rituximab monotherapy, or maintenance rituximab) and has sustained a response and remained treatment free for at least one year's duration following the last dose of rituximab received	Rituximab 375 mg/m^2 in combination with chemotherapy, up to a maximum of 8 cycles (1 dose = 1 cycle)	NDFP funding of rituximab retreatment does not apply to: • Indolent lymphoma patients who have remained treatment free for less than 12 months following the last rituximab dose used in the treatment of indolent lymphoma. • Patients with chronic lymphocytic leukemia/small lymphocytic lymphoma. NDFP funding does not extend to use of maintenance rituximab after rituximab retreatment.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				Screening for Hepatitis B virus with HbsAg and HbcAb has been completed or is in progress.
Rituximab (rit-TUCKS-ee-mab) Other name: Rituxan®	Second Line – Chronic Lymphocytic Leukemia	The patient meets criteria a and b: a. Rituximab is being used in the second line setting for relapsed or refractory chronic lymphocytic leukemia, in combination with a fludarabine-based treatment (i.e., the patient is a suitable candidate for fludarabine-based therapy). b. The patient is anti-CD20 antibody naïve (i.e., the patient has never been treated with an anti-CD20 antibody (rituximab or obinutuzumab) for chronic lymphocytic leukemia).	Cycle 1 – Rituximab 375 mg/m^2 Cycles 2 to 6 – Rituximab 500 mg/m^2	For patients with a high tumour load, consider a slower infusion rate or split dosing over 2 days. Rituximab must be used with fludarabine-based chemotherapy. Screening for Hepatitis B virus with HbsAg and HbcAb has been completed or is in progress.
Rituximab (rit-TUCKS-ee-mab) Other name: Rituxan®	In combination with idelalisib – relapsed chronic lymphocytic leukemia	The patient must meet the following criteria: Rituximab is used in combination with idelalisib for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL).	Rituximab 375mg/m^2 Day 1, Week 1, then 500mg/m^2 Day 1 on weeks 3, 5, 7, 9, 13, 17, and 21. The number of cycles funded equals 8.	• Rituximab-idelalisib is not funded as a sequential treatment option for patients whose disease has progressed on ibrutinib in the relapsed setting (and vice versa). • Patients who have experienced intolerance but not disease progression to ibrutinib in the relapsed setting may switch to rituximab-idelalisib (and vice versa). Documentation on the nature of the intolerance is required. • Rituximab is only funded if used in combination with idelalisib. • For patients with a high tumour load, consider a slower infusion rate or split dosing over 2 days during the first cycle. • The recommended dose of idelalisib is 150mg twice daily. The product monograph for idelalisib notes that idelalisib is contraindicated in first line CLL outside of a clinical trial. • Idelalisib is not funded by CCO. For patients who are eligible for Ontario Drug Benefit funding, refer to the Ministry's Exceptional Access Program for details.
Rituximab (rit-TUCKS-ee-mab) Other name: Rituxan®	Single Agent – Indolent Lymphoma	The patient must meet one of criteria a, b, c, d, and e: a. Follicular lymphoma and is unable to tolerate further chemotherapy due to hematologic toxicity b. Follicular lymphoma and has failed anthracycline or purine analog chemotherapy c. Mantle cell lymphoma	Single agent rituximab 375 mg/m^2 weekly for 4 weeks. After treatment with single agent rituximab, patients are eligible for retreatment with single agent rituximab if a durable response lasting a minimum of 12 months is achieved.	Screening for Hepatitis B virus with HbsAg and HbcAb has been completed or is in progress.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		• *Is unable to tolerate further chemotherapy* • *Is resistant or refractory to 2 or more lines of chemotherapy* • *Has failed anthracycline or purine analog chemotherapy* • Other CD20 positive low grade lymphoma (e.g., marginal zone lymphoma, lymphoplasmacytoid lymphoma (Waldenstrom's macroglobulinemia), hairy cell leukemia, mucosa associated lymphoid tissue (MALT) lymphoma but excluding diffuse small lymphocytic lymphoma/chronic lymphocytic leukemia) • *Is unable to tolerate further chemotherapy* • *Is resistant or refractory to 2 or more lines of chemotherapy* • *Has failed anthracycline or purine analog chemotherapy* e. Post-transplant lymphoproliferative disorder	Patients who have previously received rituximab in combination with chemotherapy and/or rituximab maintenance are not eligible for single agent rituximab retreatment.	
Rituximab (rit-TUCKS-ee-mab) Other name: Rituxan®	Rituximab in Combination with Chemotherapy – Indolent B-cell Lymphoma	The patient must meet criteria a, b, c, and d: a. Patient has follicular lymphoma or other indolent B-cell histology lymphoma (e.g., mantle cell lymphoma, marginal zone lymphoma, lymphoplasmacytoid lymphoma (Waldenstrom's macroglobulinemia), hairy cell leukemia, mucosa-associated lymphoid tissue (MALT) lymphoma but excluding diffuse small lymphocytic lymphoma/chronic lymphocytic leukemia) b. Patient is: • untreated, OR • has been previously treated c. Patient has <u>not</u> received previous treatment with rituximab for indolent B-cell lymphoma d. Patient will receive rituximab in combination with chemotherapy	Rituximab 375 mg/m^2 given with chemotherapy for 4-8 cycles Funded regimens: • R-CHOP • R-CVP • R-fludarabine • R-fludara-cyclo-mitoxantrone • R-cladribine • R-bendamustine • Other (Specify)	Patients previously treated with rituximab for aggressive histology lymphoma are eligible if the interval from the last dose of rituximab is greater than 1 year, provided a copy of the pathology report is submitted. Screening for Hepatitis B virus with HbsAg and HbcAb has been completed or is in progress.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Romidepsin (ROE-mi-DEP-sin) Other name: Istadax®	Relapsed or Refractory Peripheral T-Cell Lymphoma	For patients with relapsed or refractory peripheral T-cell lymphoma (PTCL) who: • are ineligible for transplant; • have undergone previous systemic therapy; and • have an Eastern Cooperative Performance Status (ECOG) of 0 to 2.	Romidepsin 14 mg/m^2 intravenously on days 1, 8, and 15 (cycle length is 28 days), until disease progression or unacceptable toxicity.	1. The following subtypes are eligible for romidepsin funding: PTCL (unspecified or NOS), angioimmunoblastic T-cell lymphoma (AITL), anaplastic large T-cell lymphoma, cutaneous gamma/delta T-cell lymphoma, hepatosplenic PTCL, enteropathy associated, T-cell lymphoma, extranodal natural killer/TCL nasal type, subcutaneous panniculitis like TCL, transformed mycosis fungoides. 2. Romidepsin funding does not apply to patients with non-transformed mycosis fungoides type of cutaneous T-cell lymphoma, Sezary syndrome, or patients with known CNS lymphoma. 3. The romidepsin eligibility criteria also applies to patients who have had prior stem cell transplant. 4. Brentuximab funding is also available for patients with the CD30+ systemic anaplastic large cell lymphoma subtype of peripheral T-cell lymphoma, provided funding criteria are met. No evidence exists to inform the optimal sequencing for brentuximab or romidepsin. The choice in sequencing should be based on a discussion between the treating hematologist and patient.
Siltuximab (sil-TUCKS-ee-mab) Other name: Sylvant®	Multicentric Castleman's Disease	The patient must meet the following criteria: • Siltuximab is used for the treatment of patients with multicentric Castleman's disease (MCD) previously treated or untreated • Patients are human immunodeficiency virus (HIV) negative • Patients are human herpes virus-8 (HHV8) negative • Treatment should be for patients with an ECOG performance status of ≤2	Siltuximab 11mg/kg IV once every three weeks until treatment failure.	1. Siltuximab is not funded for patients with HIV-positive and/or HHV8-positive multicentric Castleman's disease. 2. A clinic note should be submitted every 18 cycles, demonstrating at least stable disease and good tolerability to treatment.
Strontium 89 (STRON-tee-um) Other name: Metastron®	Palliative Bone Seeking Radiopharmaceuticals	• The patient meets all of the following criteria: • Prostate, breast or lung cancer histology • Pain poorly controlled with conventional analgesic regimens	Strontium 89: 148 mBq (4 mCi) by slow IV injection (1-2 minutes) accompanied by IV or PO hydration (at least 500 mL)	Patients with a partial response or complete response following radiopharmaceutical therapy may be considered for repeat administration for persistent or recurrent bone pain.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		• Multiple sites of uncomplicated, painful bone metastases on both sides of the diaphragm • No impending or established pathological fracture, spinal cord compression or hypercalcemia • Bone scan demonstrates activity (uptake) at the sites of painful bone metastases • Stable or absent soft tissue or visceral (liver, lung) disease • Adequate performance status (Karnofsky ≥ 60) • Adequate bone marrow reserve (WBC > 4.0 x 10^9/L; platelets > 100 x 10^9/L • Adequate renal function (BUN < 10 mmol/L; creatinine < 150 µmol/L • Adequate hepatic function (no elevation of liver enzymes) • No recent (< 4 weeks) chemotherapy or wide field radiotherapy off study • Life expectancy > 4 months, and b. A multidisciplinary assessment has been conducted by at least 2 of the 3 following specialists: radiation oncology, medical oncology, nuclear medicine		In order to avoid the risk of severe, cumulative myelosuppression, the interval between radiopharmaceutical administrations should be at least 12 weeks. For bone pain refractory to initial therapy, retreatment may be undertaken if the following is ruled out: rapid systemic disease progression, mechanical component to bone pain, underlying other bone pathology, impending or established fracture or spinal cord compression.
Temsirolimus (TEM-sir-RO-li-mus) Other name: Torisel®	Metastatic Renal Cell Carcinoma	Patient has poor risk[1] metastatic renal cell carcinoma, independent of histology, and is being treated with temsirolimus in the first line setting	Temsirolimus 25mg IV weekly until disease progression	1. Poor risk is defined using a modification of criteria from Mekhail et al (J Clin Oncol. 2005; 23:832-41). Patients must have at least 3 of the following features: a. high lactate dehydrogenase (> 1.5 times upper limit of normal); b. low hemoglobin (< lower limit of normal); c. high corrected serum calcium (> 10mg/dL); d. time from initial diagnosis to first treatment is less than 12 months; e. poor performance status (Karnofsky performance status < 80); f. metastases in multiple organ sites (e.g. lung, liver, retroperitoneal lymph nodes, etc.)

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Topotecan (toe-poe-TEE-can) Other name: Hycamtin®	Topotecan – Platinum – Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	a. Patient has previously been treated with platinum-containing chemotherapy with or without paclitaxel b. One of the following: • Disease has relapsed less than 6 months following therapy • Tumour has progressed during therapy or not responding to therapy c. Patient has reasonable performance status with symptoms that are likely to be alleviated if response is achieved	Topotecan 1.5 mg/m^2 IV for 5 days q21 days, until progression, or Topotecan 4 mg/m^2 IV weekly Days 1, 8, 15, every 28 days, until progression	Patients are eligible for treatment with either topotecan or liposomal doxorubicin. Patients having already received one of these drugs are not eligible to receive funding for the other.
Topotecan (toe-poe-TEE-can) Other name: Hycamtin®	Topotecan – Single Agent Treatment of Platinum Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer for Patients Unable to Receive Platinum Therapy	• The patient: • Platinum sensitive (Patients are considered platinum sensitive if they have had a response of 6 months or longer from the date of their last platinum containing therapy) • Has had a response of 6 months or longer from the date of the last single agent therapy b. The patient is not able to receive treatment with a platinum agent (e.g. allergy)	Topotecan 1.5 mg/m^2 IV for 5 days q21 days	Platinum sensitive patients are eligible to receive single agent paclitaxel and either liposomal doxorubicin or topotecan as a single agent.
Trastuzumab (trass-TOO-zoo-mab) Other name: Herceptin®	Gastric Cancer	a. Trastuzumab will be used in combination with intravenous 5-fluorouracil (or capecitabine) and cisplatin for the treatment of patients with HER2-positive advanced (non-resectable; either locally advanced, recurrent, or metastatic) adenocarcinoma of the stomach or gastroesophageal junction who have not received prior systemic therapy treatment for their metastatic disease b. Trastuzumab should only be administered to patients with advanced gastric cancer (non-resectable; either locally advanced, recurrent, or metastatic) whose tumours have HER2 overexpression (by IHC2+ [and confirmed by FISH+], or IHC3+, as determined by an accurate and validated assay)	Trastuzumab loading dose of 8mg/kg IV on Day 1 of the first cycle, followed by 6 mg/kg every 3 weeks until disease progression or unacceptable toxicity or withdrawal of consent	Chemotherapy may be started and trastuzumab added later provided that there has been no disease progression. Trastuzumab may be continued as a single agent until disease progression following six cycles of trastuzumab-chemotherapy. A photocopy of pathology report demonstrating HER2 overexpression (by IHC2+ [and confirmed by FISH+], or IHC3+) must be submitted to Cancer Care Ontario. The report must state clearly the hospital, date of biopsy and the hospital pathology specimen of the original material used for the test. The patient must have a normal cardiac ejection fraction. Trastuzumab should not be given concurrently with an anthracycline.
Trastuzumab (trass-TOO-zoo-mab)	Adjuvant Treatment for HER2/neu-Overexpressing Primary Breast Cancer	• The patient has tested positive for Her2/neu as per Cancer Care Ontario criteria: • IHC 3+	One of the following schedules: 4 mg/kg x 1 IV followed by 2 mg/kg IV weekly, OR 8 mg/kg x 1 IV followed by 6 mg/kg IV q3 weeks	Trastuzumab should not be given concurrently with an anthracycline. A copy of the complete surgical pathology report must be provided to NDFP, stating at minimum: the date of the

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Other name: Herceptin®		• FISH/SISH ≥2 • One of the following: • Node-positive disease • Node-negative tumor (with size > 1 cm) • The patient has received either: • adjuvant chemotherapy • neoadjuvant chemotherapy d. If the patient has received adjuvant or neoadjuvant chemotherapy not funded by NDFP, indicate the chemotherapy regimen	Trastuzumab loading dose of 4 mg/kg x 1, followed by 2 mg/kg IV weekly funded for a maximum of 54 q1 week treatments over a maximum period of 14 months. Trastuzumab loading dose of 8 mg/kg x 1, followed by 6 mg/kg IV q3 weeks funded for a maximum of 18 q3 week treatments over a maximum period of 14 months. Switching from q1 week regimen to q3 week regimen (and vice versa) is allowed assuming that the actual amount of drug is not exceeded and the 14 month period remains the same.	biopsy; the name of the hospital where the test occurred; the hospital pathology specimen number of the original materials used for the Her2/neu test; the size of the HER2 positive tumour. The results of a FISH/SISH test must be provided if the IHC test result is equivocal. The patient has a normal cardiac ejection fraction (MUGA Scan or Echocardiogram)
Trastuzumab (trass-TOO-zoo-mab) Other name: Herceptin®	Second Line – Metastatic Breast Cancer	Trastuzumab will be used for the treatment of second line HER2 positive metastatic breast cancer when given in combination with chemotherapy after previous exposure to trastuzumab based treatments in the metastatic setting	One of the following regimens: Trastuzumab loading dose of 8 mg/kg IV on Day 1 of the first cycle, followed by 6 mg/kg every 3 weeks until disease progression, unacceptable toxicity or withdrawal of consent, or Trastuzumab loading dose of 4 mg/kg IV on Day 1 of the first cycle, followed by 2 mg/kg every week until disease progression, unacceptable toxicity or withdrawal of consent	Trastuzumab will not be funded: in combination with lapatinib for the second line treatment of HER2 positive metastatic breast cancer, and/or if the patient has progressed on lapatinib for the second line treatment of HER2 positive metastatic breast cancer. Funding of second line trastuzumab for HER2-positive metastatic breast cancer will be discontinued upon evidence of further disease progression. Trastuzumab will continue to be funded if a patient had to discontinue their chemo treatment due to toxicity or intolerance. If disease progresses while on single agent trastuzumab, then further funding of trastuzumab will be discontinued. The patient must have normal cardiac ejection fraction. Trastuzumab should not be given concurrently with an anthracycline. For patients who have not received trastuzumab (adjuvant/metastatic) through the New Drug Funding Program, a photocopy of pathology report demonstrating HER2 overexpression must be submitted to Cancer Care Ontario. The report must state clearly the hospital, date of biopsy and the hospital pathology specimen of the original material used for the test.
Trastuzumab (trass-TOO-zoo-mab)	Single Agent – Metastatic Breast Cancer	• Her2/neu Status Patient must test positive for Her2/neu as per Cancer Care Ontario criteria. A photocopy of the pathology report of	Therapy should be initiated with a loading dose of 4 mg/kg, followed by 2 mg/kg IV weekly	The patient has a normal cardiac ejection fraction. There is no evidence of extensive lung involvement.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Other name: Herceptin®		the Her2/neu test must be submitted to Cancer Care Ontario. The report must state clearly the hospital, date of biopsy and the hospital pathology specimen number of the original material used for the Her2/neu test. Specify tests used for detection of Her2/neu: • IHC 3+ • FISH/ SISH ≥ 2 • Patient has metastatic breast cancer, and has received: • at least 2 chemotherapy regimens for metastatic breast cancer • anthracycline as adjuvant therapy and had 1 chemotherapy regimen as first line therapy for metastatic breast cancer • an anthracycline/taxane combination as adjuvant therapy c. Specify previous chemotherapy	Patients may be switched to 6 mg/kg IV q3 weeks after they are adequately loaded over a reasonable period of time with weekly dosing	Reimbursement will be discontinued for patients whose disease progresses while being treated with trastuzumab in the metastatic setting.
Trastuzumab (trass-TOO-zoo-mab) Other name: Herceptin®	Trastuzumab in combination with Docetaxel – Metastatic Breast Cancer	• Her2/neu Status: Patient must test positive for Her2/neu as per Cancer Care Ontario criteria. A photocopy of the pathology report of the Her2/neu test must be submitted to Cancer Care Ontario. The report must state clearly the hospital, date of biopsy and the hospital pathology specimen number of the original material used for the Her2/neu test. Please specify tests used for detection of Her2/neu: • IHC 3+ • FISH/ SISH ≥ 2. • Patient has metastatic breast cancer and (one of the following): • Cannot tolerate anthracyclines • Has failed anthracycline therapy for metastatic disease • Has received an anthracycline as adjuvant therapy	Therapy should be initiated with a loading dose of 4 mg/kg, followed by 2 mg/kg IV weekly. Patients may be switched to 6 mg/kg IV q3 weeks after they are adequately loaded over a reasonable period of time with weekly dosing.	The patient has a normal cardiac ejection fraction. There is no evidence of extensive lung involvement. Reimbursement will be discontinued for patients whose disease progresses while being treated with trastuzumab in the metastatic setting.
Trastuzumab (trass-TOO-zoo-mab) Other name: Herceptin®	Trastuzumab in combination with Paclitaxel – Metastatic Breast Cancer	• Her2/neu Status: Patient must test positive for Her2/neu as per Cancer Care Ontario criteria. A photocopy of the pathology report of the Her2/neu test must be submitted to Cancer Care	Therapy should be initiated with a loading dose of 4 mg/kg, followed by 2 mg/kg IV weekly.	The patient has a normal cardiac ejection fraction. There is no evidence of extensive lung involvement.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		Ontario. The report must state clearly the hospital, date of biopsy and the hospital pathology specimen number of the original material used for the Her2/neu test. Please specify tests used for detection of Her2/neu: • IHC 3+ • FISH/ SISH ≥ 2. • Patient has metastatic breast cancer and (one of the following): • Cannot tolerate anthracyclines • Has failed anthracycline therapy for metastatic disease • Has received an anthracycline as adjuvant therapy	Patients may be switched to 6 mg/kg IV q3 weeks after they are adequately loaded over a reasonable period of time with weekly dosing.	Reimbursement will be discontinued for patients whose disease progresses while being treated with trastuzumab in the metastatic setting.
Trastuzumab (trass-TOO-zoo-mab) Other name: Herceptin®	Trastuzumab in combination with Vinorelbine – Metastatic Breast Cancer	• Her2/neu Status: Patient must test positive for Her2/neu as per Cancer Care Ontario criteria. A photocopy of the pathology report of the Her2/neu test must be submitted to Cancer Care Ontario. The report must state clearly the hospital, date of biopsy and the hospital pathology specimen number of the original material used for the Her2/neu test. Please specify tests used for detection of Her2/neu: • IHC 3+ • FISH/SISH ≥ 2 b. Patient has metastatic breast cancer c. Patient has progressed with anthracycline or taxane therapy in the adjuvant or metastatic setting	Therapy should be initiated with a loading dose of 4 mg/kg, followed by 2 mg/kg IV weekly. Patients may be switched to 6 mg/kg IV q3 weeks after they are adequately loaded over a reasonable period of time with weekly dosing.	The patient has a normal cardiac ejection fraction. There is no evidence of extensive lung involvement. Reimbursement will be discontinued for patients whose disease progresses while being treated with trastuzumab in the metastatic setting.
Trastuzumab (trass-TOO-zoo-mab) Other name: Herceptin®	Trastuzumab with First Line Docetaxel – Metastatic Breast Cancer	The patient must meet the following criteria: a. Her2/neu Status: Patient must test positive for Her2/neu as per Cancer Care Ontario criteria. A photocopy of the pathology report of the Her2/neu test must be submitted to Cancer Care Ontario. The report must state clearly the hospital, date of biopsy and the hospital pathology specimen number of the original material used for the Her2/neu test. Please specify tests used for detection of Her2/neu: • IHC 3+ • FISH/SISH ≥ 2 b. Patient has metastatic breast cancer	Therapy should be initiated with a loading dose of 4 mg/kg, followed by 2 mg/kg IV weekly. Patients may be switched to 6 mg/kg IV q3 weeks after they are adequately loaded over a reasonable period of time with weekly dosing.	Precautions: • The patient has a normal cardiac ejection fraction • There is no evidence of extensive lung involvement Reimbursement will be discontinued for patients whose disease progresses while being treated with trastuzumab in the metastatic setting.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		c. Patient will <u>not</u> be receiving an anthracycline		
Trastuzumab Emtansine (trass-TOO-zoo-mab) Other name: Kadcyla®	Unresectable Locally Advanced or Metastatic Breast Cancer	• Trastuzumab emtansine is used for the **<u>second line treatment</u>** of HER2-positive, unresectable locally advanced or metastatic breast cancer. • The patient has an ECOG performance status of 0 or 1, and, • has either received prior treatment with trastuzumab plus chemotherapy in the metastatic setting or had disease recurrence during or within 6 months of completing adjuvant therapy with trastuzumab plus chemotherapy.	Trastuzumab emtansine 3.6 mg/kg IV every 3 weeks until disease progression or unacceptable toxicity	Publicly funded second line options include one of the following: "trastuzumab emtansine" OR "trastuzumab-other chemotherapy" OR "lapatinib-capecitabine." Trastuzumab emtansine will not be funded as a third (or later line) option if disease progression has occurred from the other second line options. A patient whose disease has progressed from first line trastuzumab and second line trastuzumab emtansine will not be eligible for funding of a third line anti-HER2 agent (e.g., "lapatinib-capecitabine or "trastuzumab-other chemotherapy"). A complete pathology report (with the date of biopsy, staging information, positive HER2 test results) must be submitted to CCO if no prior documentation has been submitted to CCO for trastuzumab funding. There is a risk of medication errors between trastuzumab emtansine and trastuzumab. Do not substitute trastuzumab emtansine for or with trastuzumab. Do not exceed the recommended trastuzumab emtansine dose (i.e., 3.6 mg/kg IV every 3 weeks). The trastuzumab emtansine dose should not be re-escalated after a dose reduction is made. It is recommended that the left ventricular ejection fraction (LVEF) be greater than or equal to 50% prior to initiation of therapy. It is also recommended that LVEF be assessed (via MUGA or ECHO) prior to the initiation of trastuzumab emtansine and at regular intervals (e.g., every 3 months) during treatment. If, at routine monitoring, the LVEF is ≤ 40%, or is 40-45% with a 10% or greater absolute decrease below the pre-treatment value, withhold the trastuzumab emtansine and repeat the LVEF assessment within approximately 3 weeks. Trastuzumab emtansine should be permanently discontinued if the LVEF has not improved or has declined further.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Trastuzumab Emtansine (trass-TOO-zoo-mab) Other name: Kadcyla®	Unresectable Locally Advanced or Metastatic Breast Cancer as Third or Subsequent Line of Treatment (Time-Limited*) *For patients who have initiated or completed at least two lines of HER2 targeted therapy prior to the implementation of this temporary funding (October 17, 2014)	• Trastuzumab emtansine is used for patients with HER2-positive, unresectable locally advanced or metastatic breast cancer with an ECOG performance status of 0 or 1, and • Who have initiated or completed at least two lines of HER2 targeted therapy prior to the implementation of this temporary trastuzumab emtansine funding (October 17, 2014), and who have not received trastuzumab emtansine in any prior line of therapy	Trastuzumab emtansine 3.6 mg/kg IV every 3 weeks until disease progression or unacceptable toxicity	Reimbursement of trastuzumab emtansine under the NDFP, according to the clinical criterion outlined above, is effective on October 17, 2014 and ends on October 16, 2017. Patients enrolled prior to the end date may continue to receive funding for treatments beyond October 16, 2017, until disease progression or unacceptable toxicity. Enrolments submitted on October 17, 2017 and later will not be considered. For this policy, the following documents may be requested: • Pathology report confirming date of biopsy, Tumour Node Metastases (TNM) staging information and positive HER2 test results There is a risk of medication errors between trastuzumab emtansine and trastuzumab. Do not substitute trastuzumab emtansine for or with trastuzumab. Do not exceed the recommended trastuzumab emtansine dose (i.e., 3.6 mg/kg IV every 3 weeks). The trastuzumab emtansine dose should not be re-escalated after a dose reduction is made. It is recommended that the left ventricular ejection fraction (LVEF) be greater than or equal to 50% prior to initiation of therapy. It is also recommended that LVEF be assessed (via MUGA or ECHO) prior to the initiation of trastuzumab emtansine and at regular intervals (e.g., every 3 months) during treatment. If, at routine monitoring, the LVEF is ≤ 40%, or is 40-45% with a 10% or greater absolute decrease below the pretreatment value, withhold the trastuzumab emtansine and repeat the LVEF assessment within approximately 3 weeks. Trastuzumab emtansine should be permanently discontinued if the LVEF has not improved or has declined further.
Vinorelbine (vin-ORE-ell-been) Other name: Navelbine®	Metastatic Breast Cancer	The patient has metastatic breast cancer and will be treated with vinorelbine and meets one of the following criteria: • cannot tolerate anthracyclines • has failed anthracycline therapy for metastatic disease • has received an anthracycline as adjuvant therapy	**No specified funded dose. For recommended dose, see CCO Drug Formulary**	The NDFP will fund only one of the 3 drugs (paclitaxel, docetaxel or vinorelbine) for any metastatic breast cancer patient. Nab-Paclitaxel may be used in place of paclitaxel or docetaxel provided that the patient meets nab-paclitaxel eligibility criteria.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Vinorelbine (vin-ORE-ell-been) Other name: Navelbine®	Adjuvant Treatment of Completely Resected Stage II or IIIa Non-Small Cell Lung Cancer	The patient has completely resected stage II or IIIa non-small cell lung cancer	Vinorelbine 25 mg/m^2 IV weekly for 16 weeks combined with cisplatin 50 mg/m^2 IV on days 1 and 8 q4 weeks x 4 cycles. Cisplatin is not funded by NDFP.	N/A
Vinorelbine (vin-ORE-ell-been) Other name: Navelbine®	Non-Small Cell Lung Cancer (NSCLC)	a. The patient has locally advanced or metastatic non-small cell lung cancer. b. One of the following: • The drug will be administered as first line (or induction) treatment • The patient has received either EGFR- or ALK-targeted therapy as their initial treatment and a non-pemetrexed platinum doublet is used as the next line of chemotherapy option (induction) • The patient has experienced excessive toxicity with another first line agent for NSCLC doses and needs to be switched to a different first line drug	**No specified funded dose. For recommended dose, see CCO Drug Formulary**	The NDFP will fund **up to 6 cycles**, based on evidence that chemotherapy given for longer than 3 to 4 cycles is not associated with improvement in overall survival, but rather may lead to worsened toxicity and a possible worsening of quality of life.
Zoledronic Acid (ZOE-le-dron-ik AS-id) Other name: Zometa®	Hormone-Refractory Prostate Cancer	a. Patient has hormone refractory prostate cancer (HRPC). (HRPC is defined as rising PSA or progression of metastatic disease in the face of castrate testosterone levels) b. Patient has asymptomatic or minimally symptomatic bone metastases. (Patients requiring strong narcotic therapy for pain control are not considered to be minimally symptomatic and are not eligible for treatment with zoledronic acid)	Zoledronic acid 4 mg IV q3 weeks	N/A

Funded Drugs and Eligibility Criteria under EBP

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Trastuzumab (trass-TOO-zoo-mab) Other name: Herceptin®	Trastuzumab (EBP) – Adjuvant Trastuzumab with Chemotherapy for HER2/neu-Overexpressing Breast Cancer Tumours Less than or Equal to 1 cm in Diameter	The patient must meet the following criteria: • For breast cancer patients with node negative HER2-positive tumours ≤ 1cm (HER2-positive defined as either IHC3+ or FISH (or SISH) ≥2).*	Trastuzumab dosing is q3 weeks (loading dose 8 mg/kg IV x1, followed by 6 mg/kg q3 weeks). The total treatment duration is one year (or the equivalent of eighteen q3 week treatments) or until limited by cardiotoxicity. Trastuzumab may be administered once weekly (or q2 weeks) for eight weeks (during the paclitaxel	a. Prior approval by CCO is required. The completed eligibility form and a baseline pathology report with the date of the biopsy, staging and other information (e.g. tumour size, tumour grade, node status, histology, hormone receptor status, HER2 status, HER2 testing information, multifocalilty, etc.), to be uploaded in the supporting documentation section. b. Left Ventricular Ejection Fraction (LVEF) results using MUGA or ECHO must be completed as follows:

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes

		*For patients with node negative HER2-positive tumours <1mm, the patient must present with multifocal disease and high risk features. A clinic note from the oncologist indicating that the patient's case has been discussed by a multidisciplinary cancer conference (MCC) along with the MCC recommendation must be submitted to CCO. If outside an MCC setting, documentation of a collaborative discussion with the advice from a pathologist and/or radiologist and the recommendation would be acceptable.
		
		• The patient is a candidate for trastuzumab-based chemotherapy;
		  • If age ≤ 50 years, LVEF ≥ 50% based on MUGA or ECHO
		  • If age > 50 years, LVEF ≥ 55% based on MUGA or ECHO
		  • No clinically significant cardiac disease
		  • Adequate marrow, renal and hepatic function
		
		• Trastuzumab will be used in combination with, or sequentially after, adjuvant chemotherapy
			component), then q3 weeks for patients receiving the dose-dense AC-Taxol regimen (weekly dosing would involve a loading dose of 4 mg/kg IV x1, followed by 2 mg/kg IV weekly; the dose for q2 weeks is the same as the q3 week dosing).	i. Before the start of trastuzumab (and after an anthracycline-based chemotherapy)
				ii. Every three months while on trastuzumab
				iii. At twelve months after completion of trastuzumab
				Should cardiac symptoms or greater than 10% absolute asymptomatic decline in LVEF occur within twelve months after completion of trastuzumab, then annual cardiac assessments following trastuzumab completion may be considered.
				
				c. Should the patient experience cardiac symptoms requiring discontinuation of trastuzumab, a cardiologic assessment documenting the ability to continue therapy must be provided to CCO when treatment is resumed.
				
				d. As a condition of participating in EBP trastuzumab, supplemental forms are required and must be submitted as follows:
				
				iv. Every six months during the first two years from the date of first treatment
				v. Every twelve months thereafter
				NOTE: Q3-month LVEF results throughout the course of trastuzumab treatments must also be reported on the supplemental forms, which can be found under the "Other Forms" tab under the patient's enrolment page.
				
				e. Trastuzumab may be used with any chemotherapy that is considered standard of care for breast cancer tumours. If the drug used in the regimen of choice is currently funded by the NDFP, the corresponding NDFP eligibility form would also need to be submitted to CCO (NDFP funding policies will apply). If TC is the regimen of choice, then completion of this form will automatically enroll the patient for the Docetaxel component of the TC, which will also be funded as part of the Evidence Building Program. If weekly paclitaxel is the regimen of choice, the cost of paclitaxel is included in the corresponding ST-QBP funding bundle and thus no NDFP enrolment is required for paclitaxel.
				
				f. If trastuzumab is discontinued for more than five weeks, prior approval must be obtained before resuming treatment (as per the HERA trial).

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				g. As of April 1, 2015, docetaxel as part of the TCH regimen is funded through the Systemic Treatment Quality-Based Program Funding Model (ST-QBP). The regimen is evidence-informed in the adjuvant/curative setting and is known as CRBPDOCETRAS. ST-QBP funds the delivery of the regimen and the drug cost for docetaxel and carboplatin for 6 cycles of treatment. NDFP funds the drug cost of trastuzumab provided patient meets funding criteria.
Oxaliplatin (ox-AL-ih-plah-tin) Other name: Eloxatin®	Oxaliplatin (EBP) – With Surgery for Curative Intent for Colorectal Cancer Patients with Resectable or Potentially Resectable Extrahepatic Metastases	Metastatic colorectal cancer (mCRC) patients deemed by a standards compliant multidisciplinary cancer conference (MCC) or 57quivalent to have one of the following: Lung metastases that are resectable or potentially resectable; OR Liver and lung metastases that are resectable or potentially resectable; OR Liver and non-pulmonary extrahepatic metastases that are resectable or potentially resectable.	Oxaliplatin used as part of FOLFOX (85mg/m^2 per cycle, up to 12 cycles) in combination with surgery for curative intent. FOLFOX is given as one of the following: "pre-op", "post-op", or "perioperative (pre- and post-op)".	a. Prior approval by CCO is required. The completed enrolment form along with documentation (e.g., a clinic note from the oncologist that the patient's case has been discussed by a multidisciplinary cancer conference or equivalent[b], including the MCC's recommendation) is required. b. If outside an MCC setting, a collaborative discussion (by the medical and hepatobiliary surgical team, with the advice of appropriate pathology, radiology), must have occurred and been documented. "Resectable" refers to a patient who is deemed suitable for surgical resection at the time of MCC discussion. "Potentially resectable" refers to a patient whose disease is initially unresectable but is expected to be become resectable after use of downstaging chemotherapy. "Unresectable" refers to a patient with a large metastatic burden, or not medically fit, with a recommendation for standard palliative treatment (usually with chemotherapy). Synchronous and metachronous metastases may be considered. (Synchronous refers to metastases found at the time of resection of the primary tumour. Metachronous refers to metastases that occur more than 6 months after resection/treatment of the primary.) Eligible patients may have had or will have R0 (curative) resection of the primary cancer. If resection does not occur (or is unsuccessful) or if use of FOLFOX is unsuccessful, the patient may be transitioned over to the usual funded metastatic regimens. mCRC patients deemed by the MCC or equivalent as being unresectable at the time of discussion are not eligible for funding under the EBP. Such patients may be eligible to receive the usual funded metastatic regimens. The funded EBP regimen consists of oxaliplatin used as part of FOLFOX (85mg/m^2, up to 12 cycles maximum). Chemotherapies **outside** of this setting will not be funded. As a condition of participating in EBP oxaliplatin, supplemental forms are required and must be submitted every six months from the date of enrolment.

Version Control Tracking

Old version no.	Date changed	New version no.	Revision
N/A	January 9, 2015	1.0	• Implemented and posted document on the Cancer Care Ontario website, replacing all NDFP and EBP web forms. All eligibility criteria are consistent with CCO eClaims as of January 9, 2015.
1.0	January 26, 2015	1.1	• Implemented *Radium-223-Dichloride – Castration-Resistant Prostate Cancer* and *Rituximab-HIV-Related Aggressive Histology B-cell Lymphoma*. All eligibility criteria are consistent with CCO eClaims as of January 9, 2015.
1.1	February 4, 2015	1.2	• Revised language in Eligibility – NDFP and Eligibility – EBP on pages 2 and 3.
1.2	February 19, 2015	1.3	• Removed notes section for *Eribulin – Metastatic or Incurable Locally Advanced – Breast Cancer*. As of February 19, 2015, supporting documentation is no longer required for the policy enrolment.
1.3	March 31, 2015	1.4	• Revised policy title of *Ipilimumab – Unresectable Melanoma* to *Ipilimumab – Previously Treated Advanced Unresectable Melanoma*, where supporting documentation is no longer required for enrolment as of April 1, 2015. • Implemented new policy *Ipilimumab – Previously Untreated Advanced Unresectable Melanoma*, effective date April 1, 2015.
1.4	April 17, 2015	1.5	• Implemented new policy *Gemcitabine and Nab-Paclitaxel – Advanced Pancreatic Cancer*, effective date April 17, 2015. • Revised policy title from *Gemcitabine – Pancreatic Cancer* to *Gemcitabine – Advanced Pancreatic Cancer*. Revised eligibility criteria, updated notes on eligibility for related policies, effective date April 17, 2015. • Revised policy titles from *Oxaliplatin and Irinotecan – Metastatic Pancreatic Adenocarcinoma* to *Oxaliplatin and Irinotecan – Advanced Pancreatic Cancer to Advanced Pancreatic Cancer (FOLFIRINOX).* Revised eligibility criteria, updated notes on eligibility for related policies, effective date April 17, 2015.
1.5	May 29, 2015	1.5	• Revised policy for docetaxel for second or subsequent line treatment of non-small cell lung cancer (NSCLC) • Implemented new policy *Docetaxel – Hormone Sensitive Prostate Cancer*
1.6	June 1, 2015	1.6	• Updated Notes section in the azacitidine policies, where supplemental form submissions have been revised to every 6 cycles, at disease progression, and when patient has discontinued treatment, effective June 1, 2015.
1.7	July 17, 2015	1.7	• Formatting and minor editing changes on various policies. These changes do not impact eligibility criteria or funding criteria. • Link to CCO Drug Formulary was added when there is no specified funded dose • Implemented new policy *Obinutuzumab – Previously Untreated Chronic Lymphocytic Leukemia*
1.7	January 6, 2016	1.8	• Added *Paclitaxel – Non-Small Cell Lung Cancer (NSCLC)* • Implemented new policy *Bevacizumab – Metastatic (Stage 4B), Persistent or Recurrent Carcinoma of the Cervix* • Implemented new policy *Romidepsin – Relapsed or Refractory Peripheral T-Cell Lymphoma* • Policy revision for *Rituximab – Second Line Chronic Lymphocytic Leukemia* • Policy revision for *Pemetrexed – Combination with Platinum for Non-Small Cell Lung Cancer* • Policy revision for *Plerixafor - Stem Cell Mobilization in Non-Hodgkin's Lymphoma or Multiple Myeloma*
1.8	March 30, 2016	1.9	• Policy revision for *Radium-223 Dichloride – Castration-Resistant Prostate Cancer* • Implemented new policy *Bevacizumab – Front-line Treatment (Previously Untreated) Ovarian, Fallopian Tube, and Primary Peritoneal Cancer (with paclitaxel and carboplatin)*

Old version no.	Date changed	New version no.	Revision
1.9	June 2, 2016	1.10	• Policy revision for *Oxaliplatin – Adjuvant High Risk Stage II or Stage III Colon or Rectal Cancer* • Implemented new policy *Pembrolizumab – Advanced Melanoma (Unresectable or Metastatic Melanoma) and no prior ipilimumab* • Implemented new policy *Pembrolizumab – Advanced Melanoma (Unresectable or Metastatic Melanoma) and prior ipilimumab*
1.10	September 9, 2016	1.11	• Implemented new policy *Aldesleukin (interleukin-2) – In-Transit Metastases from Melanoma* • Policy revision for *Liposomal Doxorubicin – Platinum – Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer* • Policy revision for *Liposomal Doxorubicin – Single Agent Treatment of Platinum Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer for Patients Unable to Receive Platinum Therapy* • Policy revision for *Paclitaxel – Single Agent Treatment of Platinum Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer for Patients Unable to Receive Platinum Therapy* • Policy revision for *Paclitaxel in Combination with Platinum – First Line – Advanced Ovarian, Fallopian Tube, or Primary Peritoneal Carcinoma* • Policy revision for *Paclitaxel in Combination with Platinum – Recurrent – Advanced Ovarian, Fallopian Tube, or Primary Peritoneal Carcinoma* • Policy revision for *Topotecan – Platinum – Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer* • Policy revision for *Topotecan – Single Agent Treatment of Platinum Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer for Patients Unable to Receive Platinum Therapy*
1.11	October 19, 2016	1.12	• Implemented new policy *Rituximab – In combination with idelalisib – relapsed chronic lymphocytic leukemia* • Policy revision for *Trastuzumab (EBP) – Adjuvant Trastuzumab with Chemotherapy for HER2/neu-Overexpressing Breast Cancer Tumours Less than or Equal to 1 cm in Diameter*
1.12	December 22, 2016	1.13	• Implemented new policy *Siltuximab – Multicentric Castleman's Disease*
1.13	February 28, 2017	1.14	• Implemented new policy *Ramucirumab – Advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma* • Policy revision for *Docetaxel – Early Operable Breast Cancer (eligibility criteria)* • Policy revision for *Trastuzumab (EBP) – Adjuvant Trastuzumab with Chemotherapy for HER2/neu-Overexpressing Breast Cancer Tumours Less than or Equal to 1 cm in Diameter (note 'e')*
1.14	March 21, 2017	1.15	• Implemented new policy *Nivolumab – Advanced Melanoma (Unresectable or Metastatic Melanoma)* • Implemented new policy *Nivolumab – Advanced or Metastatic Non-Small Cell Lung Cancer* • Implemented new policy *Nivolumab – Advanced or Metastatic Renal Cell Carcinoma and No Prior mTOR Inhibitor* • Implemented new policy *Nivolumab – Advanced or Metastatic Renal Cell Carcinoma and Prior mTOR Inhibitor*
1.15	April 24, 2017	1.16	• Implemented new policy *Blinatumomab – Acute Lymphoblastic Leukemia*
1.16	May 31, 2017	1.17	• Fixed typographical error in *Blinatumomab – Acute Lymphoblastic Leukemia*
1.17	June 29, 2017	1.18	• Policy revision for *Bevacizumab – First Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer* • Policy revision for *Cetuximab with Irinotecan – Third Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer* • Policy revision for *Irinotecan – First Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer*

Old version no.	Date changed	New version no.	Revision
			• Policy revision for *Irinotecan – Second Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer* • Policy revision for *Oxaliplatin – Adjuvant Colorectal, Small Bowel, or Appendiceal Cancer* • Policy revision for *Oxaliplatin – First Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer* • Policy revision for *Oxaliplatin – Second Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer* • Policy revision for *Oxaliplatin – With Surgery for Curative Intent for Colorectal, Small Bowel, or Appendiceal Cancer Patients with Resectable or Potentially Resectable Liver Mets* • Policy revision for *Panitumumab – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer* • Policy revision for *Raltitrexed – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer*
1.18	August 8, 2017	1.19	• Policy revision for *Azacitidine – Acute Myeloid Leukemia (AML)* (removal of requirement for supplemental forms) • Policy revision for *Azacitidine – Myelodysplastic Syndromes (MDS)* (removal of requirement for supplemental forms) • Policy revision for *Pertuzumab – In combination with trastuzumab-taxane for HER2 positive unresectable locally recurrent or metastatic cancer* (removal of requirement for supplemental forms) • Policy revision for *Trastuzumab – Single Agent Metastatic Breast Cancer* (removal of requirement for supplemental forms) • Policy revision for *Trastuzumab – In combination with Docetaxel – Metastatic Breast Cancer* (removal of requirement for supplemental forms) • Policy revision for *Trastuzumab – In combination with Paclitaxel – Metastatic Breast Cancer* (removal of requirement for supplemental forms) • Policy revision for *Trastuzumab – In combination with Vinorelbine – Metastatic Breast Cancer* (removal of requirement for supplemental forms) • Implemented new policy *Liposomal Doxorubicin ("Caelyx") Platinum-sensitive recurrent ovarian, fallopian tube, or primary peritoneal cancer*
1.19	September 1, 2017	1.20	• Implemented new policy *Panitumumab - In Combination with Chemotherapy for First Line Metastatic Colorectal, Small Bowel, or Appendiceal Cancer* • Policy revision for *Panitumumab - Metastatic Colorectal, Small Bowel, or Appendiceal Cancer* • Policy revision for *Cetuximab - Third Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer (with irinotecan)* • Policy revision for *Bevacizumab – First Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer*
1.20	September 8, 2017	1.21	• Policy revision for *Pemetrexed - Combination with Platinum for Non-Small Cell Lung Cancer* • Policy revision for *Pemetrexed - Non-Small Cell Lung Cancer (following Crizotinib)* • Policy revision for *Pemetrexed - Non-Small Cell Lung Cancer (Second or Subsequent Line)*