Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Administrative Information | References | Other Notes | Disclaimer

A - Regimen Name

GDP+OBIN Regimen

Gemcitabine-Dexamethasone-CISplatin-oBINutuzumab

Disease Site	Hematologic - Lymphoma - Non-Hodgkin's Low Grade
Intent	Palliative
Regimen Category	**Evidence-informed :** Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use. This **Regimen Abstract** is an **abbreviated** version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.
Rationale and Uses	For use in selected patients with relapsed/refractory indolent NHL (refer to NDFP form for specific criteria for obinutuzumab eligibility)
Supplementary Public Funding	**oBINutuzumab** New Drug Funding Program (Obinutuzumab - In Combination with Chemotherapy for Refractory Follicular Lymphoma)

dexamethasone
ODB - General Benefit (dexamethasone)

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B - Drug Regimen

Cycle 1:

oBINutuzumab	1000 mg	IV	Days 1, 8 and 15

Cycles 2+:

oBINutuzumab	1000 mg	IV	Day 1

Plus GDP (all cycles):

gemcitabine	1000 mg /m²	IV	Days 1 and 8
CISplatin	75 mg /m²	IV	Day 1
dexamethasone	40 mg	PO	Once daily on days 1 to 4

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C - Cycle Frequency

REPEAT EVERY 21 DAYS for up to 6 cycles unless disease progression or unacceptable toxicity (see NDFP form)

Refer to OBIN(MNT) if patients are continuing on obinutuzumab maintenance treatment.

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D - Premedication and Supportive Measures

Antiemetic Regimen: High (Day 1)
Low (Day 8)

Other Supportive Care:

Premedications (prophylaxis for infusion reactions) for obinutuzumab:

Table 1:

Treatment cycle, day	Patients	Premedication
Cycle 1, day 1	All	• IV corticosteroid*^ at least 1 hr prior to infusion • PO antipyretic** at least 30 min prior to infusion • antihistamine*** at least 30 min prior to infusion
Subsequent infusions	Patients with no IR during previous infusion	• PO antipyretic** at least 30 min prior to infusion
	Patients with grade 1 or 2 IR with previous infusion	• PO antipyretic** at least 30 min prior to infusion • antihistamine*** at least 30 min prior to infusion
	Patients with grade 3 IR with previous infusion	• IV corticosteroid**^ at least 1 hr prior to infusion

	OR patients with lymphocyte counts > 25 x 10^9/L prior to next treatment	• PO antipyretic** at least 30 min prior to infusion • antihistamine*** at least 30 min prior to infusion

*
e.g. 80 mg methylprednisolone or 20 mg dexamethasone. Hydrocortisone is not recommended as it has not been effective in reducing IR rates.
**
e.g. 1000 mg acetaminophen
***
e.g. 50 mg diphenhydramine
^ If a corticosteroid-containing chemotherapy regimen is given on the same day as obinutuzumab, the corticosteroid can be given as PO if given at least 1 hour prior to obinutuzumab, in which case additional IV corticosteroid as premedication is not required

Other Supportive Care:

- Hepatitis B screening should be performed prior to treatment for all patients.
- Patients at risk for tumour lysis syndrome should receive adequate hydration and uricostatics or alternatives starting 12 to 24 hours prior to infusion. Consider splitting the first treatment over two days for patients with high tumour burden.
- Consider withholding antihypertensives (if applicable) 12 hours prior to infusion, during infusion and for the first hour after drug administration, and withholding concomitant medications that increase bleeding risk, especially in the first cycle.
- Patients with neutropenia should receive antimicrobial prophylaxis; consider G-CSF, antiviral and antifungal prophylaxis.

Also refer to CCO Antiemetic Recommendations.

The day 1 dexamethasone dose can be given IV before chemotherapy to prevent emesis, with the oral treatment dose reduced accordingly.

- Consider use of filgrastim to maintain dose intensity for patients with febrile neutropenia or prolonged neutropenia.

- Standard regimens for Cisplatin premedication and hydration should be followed. Refer to local guidelines.

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J - Administrative Information

Outpatient prescription for home administration (dexamethasone)

Approximate Patient Visit	Day 1: Up to 8 hours; Day 8: 4 hours (first cycle), 0.75 hours (subsequent cycles); Day 15: 3 hours (first cycle only)
Pharmacy Workload (average time per visit)	41.897 minutes
Nursing Workload (average time per visit)	86.667 minutes

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K - References

Cheson BD, Chua N, Mayer J, et al. Overall survival benefit in patients with rituximab-refractory indolent non-Hodgkin lymphoma who received obinutuzumab plus bendamustine induction and obinutuzumab maintenance in the GADOLIN study. J Clin Oncol. 2018 Aug 1;36(22):2259-66.

Radford J, Davies A, Cartron G, et al. Obinutuzumab (GA101) plus CHOP or FC in relapsed/refractory follicular lymphoma: results of the GAUDI study (BO21000). Blood. 2013 Aug 15;122(7):1137-43.

Schouten HC, Qian W, Kvaloy S, et al. High-dose therapy improves progression-free survival and survivial in relapsed follicular non-hodgkin's lymphoma: results from the randomized European CUP trial. J Clin Oncol 2003;21:3918-27.

Yazdy S, Cheson BD. Impact of obinutuzumab alone and in combination for follicular lymphoma. Blood Lymphat Cancer 2017;7:73-83.

March 2020 New ST-QBP regimen

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M - Disclaimer

Regimen Abstracts

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Regimen Monographs

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

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

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