Regimen Monograph

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

A - Regimen Name

CISPDOCEFU Regimen

CISplatin-DOCEtaxel-Fluorouracil

Disease Site Gastrointestinal

Anus

Intent Palliative

Regimen Evidence-informed :

Category

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 andFirst-line treatment of metastatic or unresectable locally recurrent analUsessquamous cell carcinoma.

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CISPDOCEFU

B - Drug Regimen			
DOCEtaxel	40 mg /m²	IV	Day 1
<u>CISplatin</u>	40 mg /m²	IV	Day 1
<u>fluorouracil</u>	2400 mg /m²	IV continuous infusion over Days 1 and 2 (single dose)	

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C - Cycle Frequency

REPEAT EVERY 14 DAYS

For a usual total of 8 cycles unless disease progression or unacceptable toxicity occurs

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D - Premedication and Supportive Measures

Antiemetic Regimen:	Moderate
Febrile Neutropenia Risk:	High
NISK.	Consider G-CSF prophylaxis for patients at high risk of febrile neutropenia. See <u>G-CSF recommendations</u> .

Other Supportive Care:

- Dexamethasone 8 mg bid po for 3 days starting 1 day prior to docetaxel (prevent anaphylaxis/ fluid retention.)
- Use standard regimens for cisplatin pre-medication and hydration. Refer to local guidelines.

Also refer to <u>CCO Antiemetic Recommendations</u>.

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J - Administrative Information

Approximate Patient Visit	Day 1: 5-6 hours; 5FU only days: 0.5 hour
Pharmacy Workload (average time per visit)	37.412 minutes
Nursing Workload (average time per visit)	92.083 minutes

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K - References

Cisplatin, docetaxel, fluorouracil drug monographs, Cancer Care Ontario.

Kim S, Francois E, Andre T, et al. Docetaxel, cisplatin, and fluorouracil chemotherapy for metastatic or unresectable locally recurrent anal squamous cell carcinoma (Epitopes-HPV02): a multicentre, single-arm, phase 2 study. Lancet Oncol 2018;19:1904-1106.

April 2023 Updated DPD deficiency and fluorouracil antidote information in the Other Notes section

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L - Other Notes

DPD Deficiency Testing and Guidance:

Patients should be tested for DPD deficiency before starting treatment with fluorouracil. Refer to the <u>DPD Deficiency Guidance for Clinicians</u> for more information.

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

Antidote for Fluorouracil Overdose:

Uridine triacetate is a prodrug of uridine and is a specific antidote for treating fluorouracil overdose or severe early onset toxicities. If available, consider administering as soon as possible (i.e. within 96 hours) for suspected overdose. If not available, treatment is symptomatic and supportive.

For usage approval and supply, contact Health Canada's <u>Special Access Program</u> (SAP) (Phone: 613-941-2108. On-call service is available for emergencies). Uridine triacetate (Vistogard®) is supplied by its manufacturer in the United States (Wellstat Therapeutics).

The recommended dosing and administration for **uridine triacetate** in patients ≥18 years is:

- 10 grams (1 packet of coated granules) orally every 6 hours for 20 doses in total, without regards to meals.
- Granules should not be chewed. They should be mixed with 3 to 4 ounces of soft foods such as applesauce, pudding or yogurt.
- The dose should be ingested within 30 minutes of preparation, followed by at least 4 ounces of water.
- Refer to the prescribing information on dose preparation for NG-tube or G-tube use.

Additional resources on the management of fluorouracil infusion overdose:

- <u>Management of Fluorouracil Infusion Overdose Guideline</u> (Alberta Health Services)
- Management of Fluorouracil Infusion Overdose at the BCCA Interim Guidance (BC Cancer Agency)

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M - Disclaimer

Regimen Abstracts

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Regimen Monographs

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

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provided in the Formulary.

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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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