Regimen Monograph

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

A - Regimen Name

PEMB+TRAS(MNT) Regimen

Pembrolizumab-Trastuzumab (maintenance)

Disease Site

Gastrointestinal
Gastric / Stomach

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 maintenance treatment of patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma, after platinum and fluoropyrimidine-based chemotherapy + pembrolizumab + trastuzumab

(Refer to the NDFP eligibility form for detailed funding criteria)

Supplementary Public Funding

pembrolizumab
New Drug Funding Program (Pembrolizumab and Trastuzumab (Biosimilar) - First-line Treatment of Advanced HER2-Positive Gastric or Esophagogastric Junction Adenocarcinoma) (NDFP Website)

trastuzumab
New Drug Funding Program (Pembrolizumab and Trastuzumab (Biosimilar) - First-line Treatment of Advanced HER2-Positive Gastric or Esophagogastric Junction Adenocarcinoma) (NDFP Website)

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B - Drug Regimen

As maintenance treatment, after platinum and fluoropyrimidine-based chemotherapy + PEMB + TRAS:

pembrolizumab[1, 2]	2 mg /kg	IV (max 200 mg)	Day 1; q3 weeks
trastuzumab	6 mg /kg	IV	Day 1, q3 weeks

[1]Dosing based on NDFP funding criteria. Alternative pembrolizumab dosing is 4 mg/kg IV (max 400 mg) q6 weeks.

[2]Administer pembrolizumab prior to trastuzumab when given on the same day.

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C - Cycle Frequency

Pembrolizumab: Repeat every 3 weeks

Trastuzumab: Repeat every 3 weeks

Until disease progression or unacceptable toxicity to a maximum of 2 years (including doses given with initial chemotherapy + PEMB + TRAS), whichever comes first

Refer to NDFP form for funding criteria for retreatment.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal

Also refer to CCO Antiemetic Recommendations.

Other Supportive Care:

- Avoid the use of corticosteroids or immunosuppressants before starting pembrolizumab treatment.

Premedication (prophylaxis for infusion reactions):

Pembrolizumab:

- Routine pre-medication is not recommended.
- May consider antipyretic and H1-receptor antagonist in patients who experienced a grade 1-2 infusion reaction.

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K - References

CADTH Reimbursement Recommendation: Pembrolizumab (Keytruda). Canadian Journal of Health Technologies. July 2024

Janjigian YY, Kawazoe A, Bai Y, et al; KEYNOTE-811 Investigators. Pembrolizumab plus trastuzumab and chemotherapy for HER2-positive gastric or gastro-oesophageal junction adenocarcinoma: interim analyses from the phase 3 KEYNOTE-811 randomised placebo-controlled trial. Lancet 2023 Dec 9;402(10418):2197-208.

Pembrolizumab drug monograph, Ontario Health (Cancer Care Ontario).

Trastuzumab drug monograph, Ontario Health (Cancer Care Ontario).

December 2024 new ST-QBP regimen

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M - Disclaimer

Regimen Abstracts

A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.

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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.

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

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

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

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