OPDIVO: Indicated in both the adjuvant treatment of completely resected EC/GEJC with residual pathologic disease following neoadjuvant chemoradiotherapy and in combination with FOLFOX or CapeOX in the treatment of HER2 negative advanced or metastatic GC/GEJC/EAC[1]

Pr OPDIVO® (nivolumab)

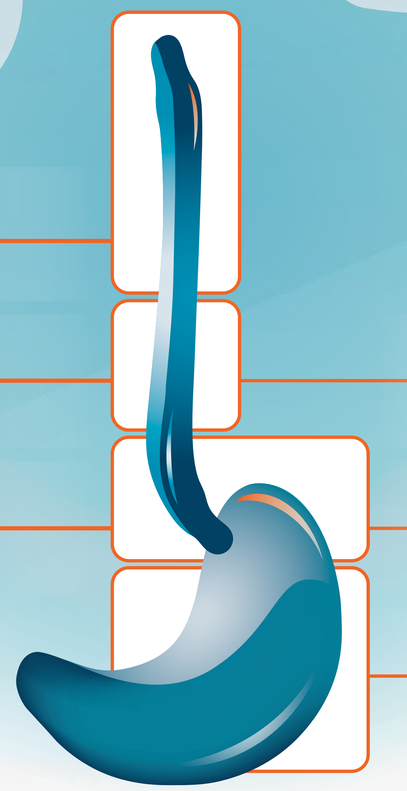
Flexible dosing regimen options for:

Now publicly funded in many provinces (criteria exist)

Treatment in completely resected

Pr OPDIVO® (nivolumab)

- **ESOPHAGEAL** Squamous
- **ESOPHAGEAL** Adenocarcinoma
- **GASTROESOPHAGEAL JUNCTION**



Treatment in advanced and metastatic

- **ESOPHAGEAL** Adenocarcinoma
- **GASTROESOPHAGEAL JUNCTION**
- **GASTRIC**

Pr OPDIVO® (nivolumab) + FOLFOX or CapeOX

NOW PUBLICLY FUNDED IN AB, BC, MB, ON, NB, NS, QC,* AND SK (CRITERIA EXIST) FOR THE FOLLOWING INDICATIONS:

OPDIVO is indicated for the adjuvant treatment of completely resected esophageal or gastroesophageal junction (GEJ) cancer in patients who have residual pathologic disease following prior neoadjuvant chemoradiotherapy (CRT).[1]

OPDIVO, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the treatment of adult patients with HER2 negative advanced or metastatic gastric, gastroesophageal junction or esophageal adenocarcinoma.[1]

GC: gastric cancer; GEJC: gastroesophageal junction cancer; EAC: esophageal adenocarcinoma.

In adjuvant treatment of completely resected esophageal or GEJ cancer

Pr OPDIVO® (nivolumab)

Recommended dosing for OPDIVO[1]

OPDIVO
Infused IV over 30 minutes

Weeks 0–16

240 mg EVERY **2** WEEKS

OR

480 mg EVERY **4** WEEKS

After 16 weeks of therapy

Administer as 480 mg every 4 weeks until disease progression or unacceptable toxicity for a total treatment duration of 1 year.

Continue treatment as long as clinical benefit is observed or until treatment is no longer tolerated by the patient.

The maximum treatment duration with OPDIVO as monotherapy for adjuvant treatment is 12 months.

Flexible dosing regimen options for **Q2W** or **Q4W** in the initial 16-week period

– Adapted from Product Monograph[1]

- If patient needs to be switched to the 480 mg dose, the first 480 mg dose should be administered two weeks after the last 3 mg/kg or 240 mg dose.
- If patient needs to be switched to the 3 mg/kg or 240 mg dose, the first 3 mg/kg or 240 mg dose should be administered four weeks after the last 480 mg dose.

Recommended dosing adjustment[1]

- For treatment with OPDIVO monotherapy or in combination with other therapeutic agents, dose escalation or reduction is not recommended. Dosing delay or discontinuation may be required based on individual safety and tolerability.
- Treatment with OPDIVO or OPDIVO in combination with ipilimumab may be continued for clinically stable patients with initial evidence of disease progression until disease progression is confirmed. Atypical responses (i.e., an initial transient increase in tumour size or small new lesions within the first few months followed by tumour shrinkage) have been observed.

Recommended treatment modifications for OPDIVO monotherapy or in combination with other therapeutic agents[1]

- When administered in combination with chemotherapy, if any agents are withheld, the other agents may be continued. If dosing is resumed after a delay:
  - Either the combination treatment, OPDIVO monotherapy or chemotherapy alone could be resumed based on the evaluation of the individual patient.

Please see the OPDIVO Product Monograph or the Product Monographs of other combination therapies for complete information on treatment modifications based on National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) v4.0.

Please see the OPDIVO Product Monograph for complete treatment modification and administration instructions.

IV: intravenous; Q2W: once every 2 weeks; Q4W: once every 4 weeks.

In treatment of advanced or metastatic GC/GEJC/EAC

Pr OPDIVO® (nivolumab)

Recommended dosing for OPDIVO in combination with fluoropyrimidine- and platinum-containing chemotherapy[1]

Administer OPDIVO followed by chemotherapy on the same day

OPDIVO
Infused IV over 30 minutes
In combination with fluoropyrimidine- and platinum-containing chemotherapy (i.e., FOLFOX or CapeOX)

240 mg EVERY **2** WEEKS
with fluoropyrimidine- and platinum-containing chemotherapy every 2 weeks

OR

360 mg EVERY **3** WEEKS
with fluoropyrimidine- and platinum-containing chemotherapy every 3 weeks

Treatment is recommended until disease progression or unacceptable toxicity.

The maximum treatment duration for OPDIVO is 2 years.

Flexible dosing regimen options for **Q2W** or **Q3W**

– Adapted from Product Monograph[1]

Recommended dosing adjustment[1]

- For treatment with OPDIVO monotherapy or in combination with other therapeutic agents, dose escalation or reduction is not recommended. Dosing delay or discontinuation may be required based on individual safety and tolerability.
- Treatment with OPDIVO or OPDIVO in combination with ipilimumab may be continued for clinically stable patients with initial evidence of disease progression until disease progression is confirmed. Atypical responses (i.e., an initial transient increase in tumour size or small new lesions within the first few months followed by tumour shrinkage) have been observed.

Recommended treatment modifications for OPDIVO monotherapy or in combination with other therapeutic agents[1]

- When administered in combination with chemotherapy, if any agents are withheld, the other agents may be continued. If dosing is resumed after a delay:
  - Either the combination treatment, OPDIVO monotherapy or chemotherapy alone could be resumed based on the evaluation of the individual patient.

Please see the OPDIVO Product Monograph or the Product Monographs of other combination therapies for complete information on treatment modifications based on National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) v4.0.

Please see the OPDIVO Product Monograph for complete treatment modification and administration instructions.

IV: intravenous; Q2W: once every 2 weeks; Q3W: once every 3 weeks.

Pr OPDIVO® (nivolumab)

* The reimbursement criteria under RAMQ† are as follows:

- OPDIVO (nivolumab) when used in monotherapy for adjuvant treatment of completely resected esophageal or gastroesophageal junction (GEJ) cancer in patients who:
  - have completely resected cancer and residual pathologic disease following prior neoadjuvant chemoradiotherapy, and
  - underwent resection within 16 weeks, and
  - have an ECOG performance status of 0 or 1.

  The maximum duration of treatment is 12 months.
- OPDIVO (nivolumab) when used in combination with fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of advanced, non-resectable, or metastatic gastric, gastroesophageal junction or esophageal cancer, in patients:
  - with adenocarcinoma and HER2 negative status, and
  - who have an ECOG performance status of 0 or 1.

  The maximum duration of each authorization is 4 months.

  When requesting authorization to continue therapy, the physician will be required to provide evidence of clinical benefit through the absence of disease progression according to iRECIST criteria, confirmed by imaging.

  The maximum duration of treatment is 24 months.

  Note that nivolumab is not approved following failure of an antibody targeting PD-1 or PDL1 if it was administered for the adjuvant treatment of esophageal or gastroesophageal junction cancer. In this case, failure is defined as disease progression during adjuvant therapy or within 6 months of discontinuation.

† Official Mark of the Régie de l'assurance maladie du Québec.

Please consult the OPDIVO Product Monograph at http://www.bmscanada.ca/en/pm/OPDIVO_EN_PM.pdf for indications, contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The Product Monograph is also available by calling us at: 1-866-463-6267.

Reference: 1. OPDIVO Product Monograph. Bristol-Myers Squibb Canada Co.

Bristol Myers Squibb™