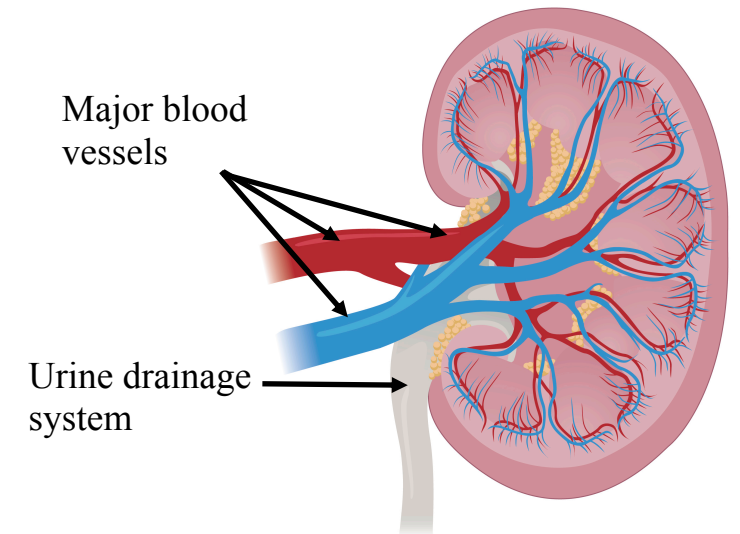


# SHOULD I RECEIVE PEMBROLIZUMAB AFTER KIDNEY CANCER SURGERY TO PREVENT CANCER FROM COMING BACK?

A decision aid to discuss a medical treatment option with your doctor

- This decision aid was created to educate people who recently underwent surgery to remove a cancerous kidney tumour and may be eligible to receive additional medical treatment.
- Additional treatment after cancer surgery when there is no sign of remaining cancer is called adjuvant therapy. The goal of adjuvant therapy is to prevent or delay cancer from returning and potentially to prolong patients' lives.
- All patients are unique. There are no wrong decisions.
- This decision aid can help you discuss treatment options with your doctor when determining how to best proceed with your care after surgery.

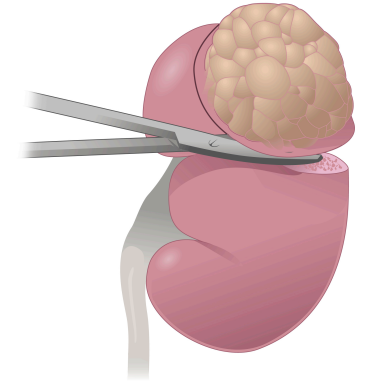
## Normal Kidney Anatomy



# SHOULD I RECEIVE PEMBROLIZUMAB AFTER KIDNEY CANCER SURGERY TO PREVENT CANCER FROM COMING BACK?

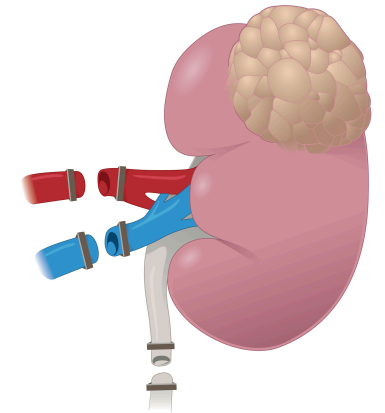
## This decision aid may be for you if:

- You had a kidney cancer surgery within the last 12 weeks.
- You had a cancerous kidney tumour that was large (>7 cm) and/or growing into tissues (fat, blood vessels) around the kidney.
- You had kidney cancer that had spread to the lymph nodes around the kidney or into another organ which were removed during surgery.
- This includes some patients with stage 2, most patients with stage 3 and some patients with stage 4 kidney cancer.



## This decision aid may not be for you if:

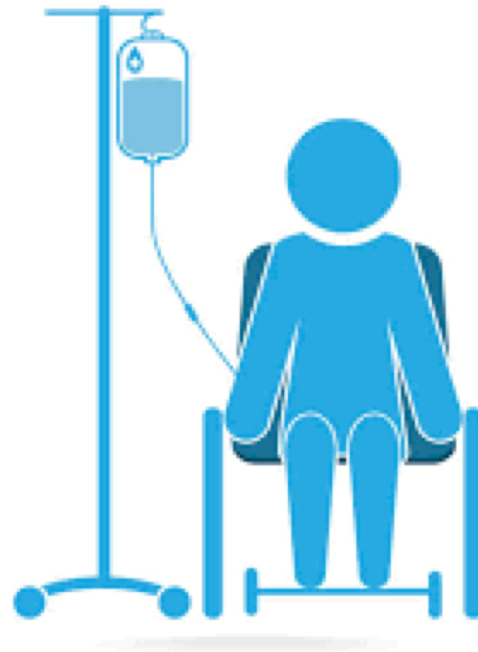
- You had kidney cancer surgery more than 12 weeks ago.
- You had a small, cancerous kidney tumour removed (<7 cm) and/or it was not growing into the tissues (fat, blood vessels) around the kidney.
- You have kidney cancer that has spread to other parts of your body (metastatic).
- This includes all patients with stage 1, most patients with stage 2 and most patients with stage 4 kidney cancer.



***If you are not sure if this decision aid applies to you, please ask your doctor.***

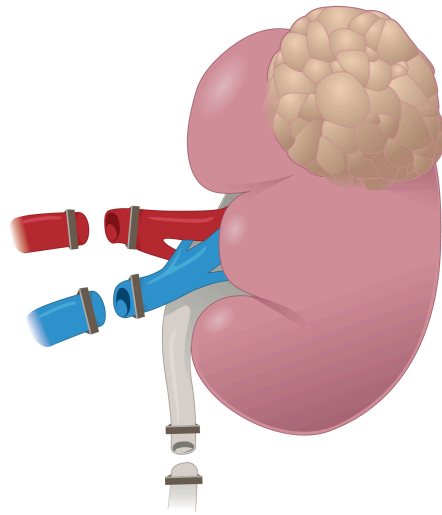
## What is Pembrolizumab?:

- Pembrolizumab is a type of medication known as immunotherapy.
- ‘Pembrolizumab’ is the generic name for the drug and ‘Keytruda’ is the trade name. Both are the same medication.
- Immunotherapy works by enhancing your body’s natural immune cells to fight unwanted cells like cancer cells.
- Pembrolizumab is given through an intravenous approximately every 3 weeks for up to 1 year.
- When treatment (like pembrolizumab) is given after surgery, it is called adjuvant therapy.



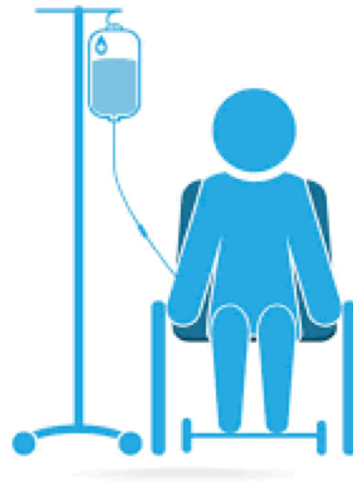
## Which patients are eligible to receive pembrolizumab after kidney cancer surgery?

- Your doctor will discuss with you if it is an option for you to receive pembrolizumab after kidney cancer surgery.
- Patients who had a very large, cancerous kidney tumour (>7 cm), a tumour that was growing into the tissues (fat, blood vessels) around the kidney, kidney cancer in the lymph nodes or another organ that were removed during surgery may be eligible to receive pembrolizumab after surgery.
- Patients must be within 12 weeks of their kidney cancer surgery to receive adjuvant pembrolizumab.



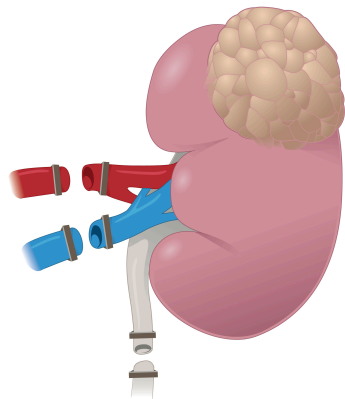
## **Understanding the research on pembrolizumab after kidney cancer surgery:**

- One study examined the benefits and risks in eligible patients who received pembrolizumab after kidney cancer surgery compared to patients who did not receive pembrolizumab.
- The study showed that on average, patients who receive pembrolizumab after kidney cancer surgery, were more likely to have a longer period of time without kidney cancer returning than patients who do not receive pembrolizumab (see page 11 for details). Another way to say this, is that this study showed that pembrolizumab delays kidney cancer from returning.
- The study also showed that some patients who receive pembrolizumab after kidney cancer surgery, are more likely to live longer on average compared to patients who do not receive pembrolizumab.
- In the study, patients who had the highest risk of kidney cancer returning, had the most benefit from receiving pembrolizumab after surgery. To better understand your risk of kidney cancer returning, please ask your doctor.
- The side effects (negative events) of pembrolizumab are further discussed on page 12 of this decision aid.



## **Understanding the research on other medical treatments after kidney cancer surgery:**

- There have been several other studies that examined the benefits and risks in patients who received other medications (like pembrolizumab) after kidney cancer surgery.
- These other studies did not show an improvement in the number of patients who had kidney cancer return or how long patients lived whether they received the medication or not.
- Only the study that evaluated pembrolizumab showed improved survival and a delay in the return of kidney cancer after surgery. Therefore, pembrolizumab is the only medication available for patients to receive after kidney cancer surgery with the goal of preventing the kidney cancer from returning and increasing how long patients live at this time.



# What options do I have after my kidney cancer surgery?

The following are management options for patients who have received kidney cancer surgery for a large tumour, a tumour that was growing into the tissue (fat, blood vessels) surrounding the kidney or had kidney cancer that was in the lymph nodes or other organs and removed during surgery. These options are presented in no specific order. Each of these options have benefits and risks that are important to consider when you are thinking about the best treatment option for you.

## Receive pembrolizumab and monitoring



## Receive monitoring (No pembrolizumab)



# What options do I have after my kidney cancer removal surgery?

## Receive pembrolizumab and monitoring:

- Pembrolizumab is an intravenous medication that is given approximately every 3 weeks for up to 1 year after surgery for patients with an increased risk of cancer recurrence.
- Patients who receive pembrolizumab will be followed with regular medical appointments, blood tests and imaging tests (example CT scans) to monitor for kidney cancer recurrence. These appointments will be every 3-6 months.
- Although many patients receive pembrolizumab without problems, some patients will develop side effects requiring additional treatment/medication they may have to take for the rest of their life. These side effects (negative events) are discussed on page 12.
- If kidney cancer does return after receiving pembrolizumab, patients are able to receive additional types of intravenous and/or oral treatments. However, the additional types of treatments available may be fewer for patients who receive pembrolizumab after surgery compared to those who do not receive pembrolizumab after surgery. This is especially true if the cancer returns while a patient is receiving pembrolizumab or shortly after finishing treatments (less than 6 months). Some patients may not be able to receive the standard immunotherapy medications given to patients when kidney cancer returns (ex ipi/nivo or pembro/axitinib).
- Some patients may also be able to have additional surgery, radiation or other treatment to control the cancer if it does return.





# What options do I have after my kidney cancer surgery?

## Receive monitoring (No pembrolizumab):

- Patients who do not receive pembrolizumab will be followed with regular medical appointments and imaging tests (example CT scans) to monitor for kidney cancer recurrence. These appointments will initially be every 3-6 months. There will be fewer appointments overall, as there will be no appointments to receive intravenous medication.
- If kidney cancer does return, patients often receive intravenous treatments like pembrolizumab and/or oral treatments (example axitinib) at that time. By not receiving pembrolizumab after surgery, patients would be less limited in the number of options for medications they can receive if the kidney cancer does return.
- Some patients may also be able to have additional surgery, radiation or other treatments to control the cancer if it does return. When cancer returns, it could still be in the kidney or the kidney cancer could have spread to other parts of the body.
- Patients who do not receive pembrolizumab will not be at risk of developing side effects of the medication as they are not receiving it.
- Other clinical trials may be available to you and can be discussed with your doctor.



## What factors may affect whether you can receive pembrolizumab?:

Circle yes or no and discuss your other health factors with your doctor.

	Yes or No		Comment
Are you pregnant, breastfeeding or planning to become pregnant?	Yes	No	
Do you have renal failure / kidney disease?	Yes	No	
Do you have any autoimmune disorders? (examples include rheumatoid arthritis, Lupus, Crohn's disease)	Yes	No	
Do you have liver disease or liver failure?	Yes	No	
Have you received radiation to the kidneys?	Yes	No	
Do you take immunosuppressant medications?	Yes	No	
Do you have any other cancers? (in addition to kidney cancer)	Yes	No	
Do you have human immunodeficiency virus (HIV), tuberculosis or hepatitis?	Yes	No	
Have you previously received a transplant?	Yes	No	
Do you use alcohol or recreational drugs daily?	Yes	No	

Other comments related to your health:

**Working through the 4 steps of this decision aid may help you consider the options.**

**Step 1: What are the benefits and risks of each management option?**

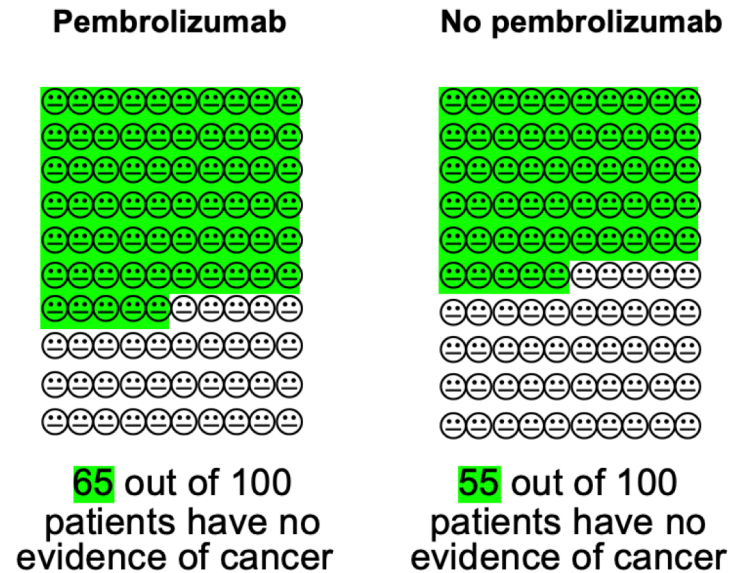
Every patient is unique. No one can predict the exact outcome of your chosen option. These diagrams have blocks of 100 faces that show a 'best estimate' of what happens to **100 people** who have received kidney cancer surgery for a large tumour, a tumour that was growing into the tissue around the kidney, kidney cancer in the lymph nodes or another organ that was removed during surgery, and either received pembrolizumab or did not.

Each face (😊) stands for one person. The shaded areas show the average number of people affected based on current research. There is no way of knowing in advance if you will have these benefits or risks. However, individual factors may help your physician predict your risk. These outcomes could happen at any time, but research has not been done to show what the estimates are beyond 4.5 years.

**Benefits: Patients with positive results from the given treatment highlighted in green.**

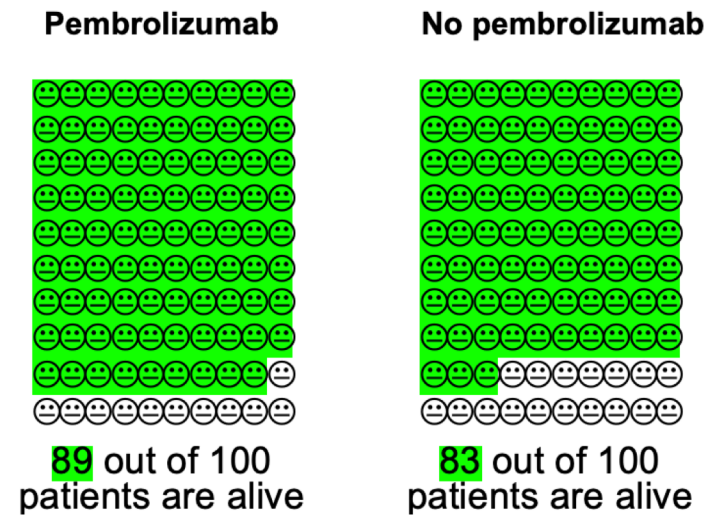
**Benefit – No detectable kidney cancer after 4.5 years of follow-up**

After receiving pembrolizumab or not receiving pembrolizumab, the likelihood of having no detectable kidney cancer after 4.5 years of follow-up is<sup>2</sup>:



**Benefit – Alive after 4.5 years of follow-up**

After receiving pembrolizumab or not receiving pembrolizumab, the likelihood of being alive after 4.5 years of follow-up is<sup>2</sup>:



**Disadvantages: Patients with negative events from the given treatment highlighted in yellow.**

**Risk – Serious negative event that could require additional treatment and could affect your quality of life:**

Receiving pembrolizumab can cause serious negative events that require some (but not all) patients to take medications for the rest of their lives or that can affect their quality of life.

These can also be called side effects. After 4.5 years of follow-up, the likelihood of a serious (Grade 3-5 out of 5) negative event are<sup>1,2</sup>:

**Pembrolizumab**



**21** out of 100 patients have a serious negative event

**No pembrolizumab**



**12** out of 100 patients have a serious negative event

The most common negative event (side effect) was fatigue in both groups.

Other **serious negative events** that were seen in the group of patients who received pembrolizumab were<sup>2</sup>:

-decreased kidney function (1-2%)

-diarrhea (2%)

-new onset diabetes (1%)

-adrenal failure (1-2%)

-bowel inflammation (1%)

-skin rash (1-2%)

These are considered serious negative events and some (but not all) would require additional medications and monitoring blood work for the rest of the patients' life. One example, is developing diabetes and needing to take insulin for the rest of your life. This is a rare (1%) but possible serious side effect of pembrolizumab.

Over-treatment may be another disadvantage of receiving pembrolizumab. Some patients who receive pembrolizumab after surgery would never have had their kidney cancer return, therefore, they received treatment they did not need. However, it is not possible to know ahead of time, which patients will be cured with surgery and which patients will have cancer come back.

## Step 2: What matters to you?

Common reasons to choose each option are listed below.

Check ✓ how much each reason matters **to you** on a scale from 0 to 5.

**'0'** means the reason is **not** important to you. **'5'** means it is **very** important to you

### Reasons to choose:

#### Receive pembrolizumab and monitoring

Not Important

Very Important

How important is it for you to not have kidney cancer come back?

①

②

③

④

⑤

⑥

How important is it for you to receive every treatment possible to treat your cancer?

①

②

③

④

⑤

⑥

#### Receive monitoring (No pembrolizumab)

Not Important

Very Important

How important is it for you to avoid multiple medical appointments and hospital visits?

①

②

③

④

⑤

⑥

How important is it for you to avoid long term negative effects (side effects) that may require additional medications for the rest of your life?

①

②

③

④

⑤

⑥

Are there other questions you have for your doctor? If yes, please write them down here.

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## Step 3: What else do you need to prepare for decision making?

Find out how well this decision aid helped you learn the key facts.

Check  the best answer.

	Pembrolizumab	No pembrolizumab	Both options	Not sure
1. Which option decreases the chance that kidney cancer will come back within 4.5 years of follow-up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Which option has a higher risk of serious side effects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Which option is available to patients who have received kidney cancer surgery to remove a large tumour or a tumour growing into the tissue around the kidney?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Which option has fewer medical appointments after surgery?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



## Find out how comfortable you feel about deciding



**Do you know the benefits and risks of each option?**

**Yes**

**No**



**Are you clear about which benefits and risks matter most to you?**



**Do you have enough support and advice to make a choice?**



**Do you feel sure about the best choice for you?**

If you answered 'No' to any of these, discuss with your doctor

(The SURE Test © O'Connor & Légaré, 2008)

Answers for the key facts: 1. Pembrolizumab, 2. Pembrolizumab, 3. Both options, 4. No pembrolizumab

## Step 4: What are the next steps?

Check  what you prefer.

- I prefer to receive pembrolizumab and monitoring.
- I prefer to receive monitoring (no pembrolizumab).
- I need to discuss the options with my doctor and family.
- I need to read more about my options.
- Other, please specify: \_\_\_\_\_

# This information is not intended to replace the advice of a health care provider.

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**Content editors:** Kristen McAlpine, MD, FRCSC, Christine Collins, Simon Tanguay, MD, FRCSC, Aly-Khan Lalani, MD, FRCPC, Lori Wood, MD, MSc, FRCPC, Christian Kollmannsberger, MD, FRCPC, Jennifer Jones, MD, PhD, FRCPC, Rahul Bansal, MD, MCh, FRCSC, Dawn Stacey, RN, PhD, CON(C), Luke T. Lavallée, MDCM, MSc, FRCSC.

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**SMOG readability rating: 11.1 (7<sup>th</sup> grade)**

## **Benefits and risks data from:**

1. Powles T, Tomczak P, Park S, et al. Pembrolizumab versus placebo as post-nephrectomy adjuvant therapy for clear cell renal cell carcinoma (KEYNOTE-564): 30-month follow-up analysis of a multicenter, randomized, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncology*. 2022;23:1133-44. doi: [http://doi.org/10.1016/S1470-2045\(22\)00487-9](http://doi.org/10.1016/S1470-2045(22)00487-9).
2. Choueiri T, Tomczak P, Park S, et al. Overall survival with adjuvant pembrolizumab in renal-cell carcinoma. *N Engl J Med*. 2024;390(15):1359-71. doi:10.1056/NEJMoa2312695.