

Understanding Immunotherapy

A guide for people affected by cancer

This fact sheet has been prepared to help you understand more about immunotherapy, a treatment offered to some people with cancer. The main type of immunotherapy for cancer uses drugs called checkpoint inhibitors. Most of the information in this fact sheet relates to checkpoint inhibitors.

What is immunotherapy?

Immunotherapy is a treatment that uses the body's own immune system to fight cancer. There are several different types of immunotherapy.

Checkpoint inhibitors help the immune system to recognise and attack cancer cells (see page 2). Examples include pembrolizumab, nivolumab, ipilimumab, atezolizumab, durvalumab and avelumab. New checkpoint inhibitor drugs may become available in the future.

Other types of immunotherapy stimulate the immune system to help it work better against cancer. These include immune stimulants, chimeric antigen receptor (CAR) T-cell therapy and monoclonal antibodies. For details, see page 3.

Immunotherapy may be used on its own or with other cancer treatments. A combined immunotherapy drug is also now available (for people with advanced melanoma). Immunotherapy can be given as the first treatment, or when the cancer has not responded to or has come back after other treatments.

How the immune system works

The immune system is a network of cells, chemicals, tissues and organs. It includes the lymph nodes, spleen, thymus, tonsils and bone marrow, as well as white blood cells known as lymphocytes.

This network tries to protect the body from infections and from abnormal cells such as cancer cells. When a germ enters the body, or when a cell becomes abnormal, the immune system usually recognises and then attacks the germ or cell so that it does not harm the body. This is called an immune response. The immune system can remember every germ or abnormal cell it has attacked so it can easily recognise them if they appear in the body again.

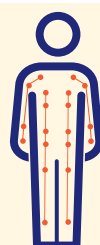
Immunotherapy and the immune system

To keep you healthy, the immune system needs to be carefully balanced. If it is too weak, you will be prone to infection and disease. If it is too active, it can start to attack normal cells and lead to autoimmune diseases such as rheumatoid arthritis and lupus.



Tipping the balance

Cancers find ways to disrupt the balance of the immune system so that it does not see cancer cells as abnormal. Immunotherapy manipulates the immune system to restore the balance and allow it to recognise and attack the cancer.



Immune system side effects

If immunotherapy makes the immune system overactive, it may affect normal cells as well as cancer cells. This means you can get side effects anywhere in the body (see pages 5-7).



After treatment

The immune system has a "memory", so immunotherapy sometimes keeps working long after treatment finishes. This means side effects can appear months or even years after treatment, and some can be long term.

Cancer and the immune system

Cancer starts when abnormal cells begin growing out of control. The immune system usually stops new cancers from developing because it recognises abnormal cells and destroys them. When the body's immune response is not able to kill all the abnormal cells, these cells can develop into cancer.

The immune system has natural mechanisms ("checkpoints") that prevent it from becoming too strong and attacking healthy cells and tissue. Some cancers take over these checkpoints and use them to prevent the immune system from attacking the cancer cells.

Cancers may also change over time (mutate), which helps them to "hide" from the immune system. This is why treating cancer isn't as simple as boosting the immune system. Modern immunotherapy drugs try to help the immune system in very specific ways.

Some people with cancer wonder if they should try special diets or supplements to boost the immune system so it can fight the cancer. While having a healthy diet is always important, extreme diets are not proven to be effective and can be harmful. Talk to your doctors before starting any special diets or taking supplements during cancer treatment.

How cancer is treated

Because each cancer is unique, people may have different treatment plans, even if their cancer type is the same. The 3 most common cancer treatments are:

- surgery
- chemotherapy
- radiation therapy (also called radiotherapy).

Other, newer treatments used for some types of cancer include:

- immunotherapy
- targeted therapy
- hormone therapy.

Chemotherapy, targeted therapy, immunotherapy and hormone therapy are all drug therapies. They are known as systemic treatment because the drugs circulate throughout the body.

Cancer treatments may be used on their own or in combination. For example, you may have surgery to remove a tumour, followed by immunotherapy to stop the cancer returning. Doctors will recommend the best treatment for you based on the type and stage of the cancer, its genetic make-up, your age and your general health.

- ▶ See our information on surgery, chemotherapy, radiation therapy and targeted therapy.

How checkpoint inhibitors work

The white blood cells known as lymphocytes are an important part of the immune system. There are 2 main types of lymphocytes – T-cells and B-cells. They travel through the body looking for germs and abnormal cells and work together to destroy them.

Checkpoint inhibitors help T-cells to recognise and attack cancer. The table below gives a simplified explanation of this process.

T-cells and checkpoint inhibitors

What T-cells usually do

Your immune system's T-cells circulate throughout the body looking for abnormal cells to destroy. The T-cells carry "checkpoints", special proteins with names such as PD-1, PD-L1 and CTLA-4.

What checkpoints usually do

Checkpoints act as natural brakes to stop T-cells destroying healthy cells.

How some cancer cells use checkpoints

In some people, cancer cells use checkpoints to stop T-cells from seeing the cancer cells as abnormal.

What checkpoint inhibitors do

Checkpoint inhibitors are special drugs that block these checkpoints so that the T-cells can once again find and attack the cancer.

See pages 3-7 for more information about having checkpoint inhibitors as part of your cancer treatment, including common and rare side effects.

Other types of immunotherapy

While checkpoint inhibitors are the main type of immunotherapy, there are some other types that work in different ways. Several types of immunotherapy have been approved to treat particular cancers, and some are still being tested in clinical trials. Your cancer specialist can give you the latest information.

Type	How it works	Examples
immune stimulants	These treatments stimulate the immune system to attack cancer.	- Bacillus Calmette-Guérin (BCG) – a vaccine put directly into the bladder to prevent bladder cancer coming back or spreading - imiquimod – a cream applied directly to some skin cancers
chimeric antigen receptor (CAR) T-cell therapy	CAR T-cell therapy boosts the ability of T-cells to fight the cancer. T-cells are removed from the blood and altered so they can better recognise cancer cells. The altered T-cells are then returned to the blood through an intravenous drip (infusion).	- used for some types of leukaemia that have come back or not responded to treatment - clinical trials are testing whether CAR T-cell therapy works well for other types of cancer - available only in a few public hospitals at this stage
monoclonal antibodies	The body's immune system makes proteins called antibodies to help fight infections. Monoclonal antibodies are manufactured (synthetic) versions of natural antibodies. Some of these drugs are also classified as targeted therapy. ► See our <i>Understanding Targeted Therapy</i> fact sheet.	- trastuzumab – used for some types of breast cancer and stomach and oesophageal cancers - pertuzumab – used for some types of breast cancer - rituximab – used for some types of leukaemia and some types of non-Hodgkin lymphoma

Vaccines to prevent cancer

Some vaccines are not used to treat cancer but can help prevent it. They do this by training the immune system to attack viruses that have been linked to certain cancers. The human papillomavirus (HPV) vaccine helps prevent cervical cancer, and also offers some protection against anal and penile cancers and some head and neck cancers. You can read more about the HPV vaccine at hpvvaccine.org.au. Vaccines against the hepatitis B virus help prevent liver cancer. Visit health.gov.au and search for "hepatitis B vaccine" for more information.

Is checkpoint inhibitor therapy right for me?

Checkpoint inhibitors can be used for many types of cancer. Some checkpoint inhibitors are now available for any type of advanced cancer suitable for this treatment. Checkpoint inhibitors are also available in certain situations for some early-stage cancers, including lung and breast cancer.

Checkpoint inhibitors work well for some people, but not for everyone. To work out if checkpoint inhibitor therapy is an option for you, your cancer specialist

will consider the type and stage of cancer, any gene changes or other features in the cancer cells, the available evidence, your treatment history, your future treatment options and your overall health.

Even after all these factors are considered, it is difficult to predict whether checkpoint inhibitor therapy will work. The rate of success varies greatly depending on the type of cancer and many individual factors. You can ask your specialist how successful the treatment has been for people with the same type of cancer as you.

Challenges of checkpoint inhibitor therapy

Will it work? – The most challenging issue is that this type of therapy doesn't work for everyone. If checkpoint inhibitor therapy is an option for you, ask your specialist how likely the cancer is to respond to the treatment and what other treatments are available. To make checkpoint inhibitor and other immunotherapy available to more people in the future, researchers are trying to understand why some cancers respond better than others.

How long will it take to work? – Like most other cancer treatments, checkpoint inhibitor therapy usually takes a while to work. Depending on how your immune system and the cancer responds, checkpoint inhibitors can take weeks or months to start working. Sometimes they keep working long after treatment stops, but this varies from person to person.

How will I feel? – You and your family may feel anxious while waiting to see whether you'll respond to the treatment. If it does work, you may worry about how long checkpoint inhibitors will control the cancer or whether the cancer will come back.

You may feel it is hard to make plans about work, relationships and travel. Many people find comfort in everyday activities; others focus on doing things they've always wanted to do. Let your cancer nurse or specialist know how you're feeling. They may connect you with a psychologist who can help you work through your thoughts.

► See our *Emotions and Cancer* booklet.

How much will it cost? – Checkpoint inhibitors are expensive (often several thousand dollars per dose). The Australian Government covers most of this cost for some checkpoint inhibitors through

the Pharmaceutical Benefits Scheme (PBS). New checkpoint inhibitors may be added to the PBS in the future. Your specialist can give you the latest information about which drugs are on the PBS.

What if it's not on the PBS? – You may be able to get checkpoint inhibitors through clinical trials or, sometimes, through a compassionate access program or cost-share program offered by the pharmaceutical company.

Some people choose to pay the entire cost themselves, but this can be a major financial decision. Before deciding to pay for any cancer treatment, it is important to fully understand the total cost, as well as the likely rates of success and the possible risks and benefits of the treatment. Take the time to discuss this with your cancer specialist and your family or close friends.

How checkpoint inhibitors are given

Checkpoint inhibitors are prescribed by a medical oncologist (a doctor who treats cancer with drug therapies) or haematologist (a doctor who treats blood cancers). They are given as a liquid through a drip inserted into a vein (intravenous infusion). Sometimes 2 or more drugs may be given together, such as 2 checkpoint inhibitors, or a checkpoint inhibitor with 1–2 chemotherapy drugs or a targeted therapy drug.

You will usually have treatment as an outpatient, which means you visit the hospital or treatment centre for the infusion and then go home again. Checkpoint inhibitors are usually given in repeating cycles, with rest periods of 2–6 weeks between cycles.

How often and how long you have the treatment depends on the type of cancer, the type of checkpoint inhibitor, how the cancer responds to the treatment, and what side effects you may experience. Many people stay on checkpoint inhibitors for up to 2 years. Clinical trials are underway to test whether ongoing treatment is needed or if checkpoint inhibitor therapy can be given for a shorter period of time once it has started working.



If one checkpoint inhibitor drug doesn't work or stops working, ask your cancer specialist about your other treatment options. You may be able to try another type of checkpoint inhibitor drug or join a clinical trial. A clinical trial is a research study that tests new or modified treatments to see if they are better than current approaches.

Most cancers have treatment protocols that set out which drugs to have, how much and how often. You can find information about protocols for checkpoint inhibitors and other cancer drugs at eviq.org.au, which provides cancer treatment information (visit eviq.org.au). Your specialist may need to tailor the protocols to your individual situation.

Like many other cancer treatments, checkpoint inhibitor drugs are often not safe to use if you are pregnant or breastfeeding. Ask your doctor for advice about contraception. If you become pregnant, let your medical team know immediately.

What if I have an autoimmune disease? – It is important to tell your cancer specialist if you have an autoimmune disease such as rheumatoid arthritis, lupus, ulcerative colitis or Crohn's disease. You may still be able to have immunotherapy, but there will be extra issues to consider.

Autoimmune diseases make the body's immune system overactive so it attacks normal cells, causing redness, swelling and pain (inflammation). The extra immune system activity caused by checkpoint inhibitors can make these symptoms worse.

What if I've had an organ transplant? – If you have had an organ transplant, you will probably be taking medicines that suppress the immune system and stop your body from rejecting the new organ. Talk to your specialists, as they will need to carefully balance these medicines with the extra immune system activity caused by checkpoint inhibitors.

Side effects of checkpoint inhibitors

Like all treatments, checkpoint inhibitors can cause side effects. These are sometimes called immune-related adverse events (irAEs).

Checkpoint inhibitor side effects are different to the side effects of other cancer treatments and need to be managed differently.

The diagram on the next page shows some possible side effects of immunotherapy, but you are unlikely to have all of the side effects shown.

“Immunotherapy treatment involved adapting to new drugs and managing side effects with my oncology team.” JASON

When to expect side effects

You may have side effects within days of starting treatment, but more commonly they occur several weeks or months after starting treatment. In rare cases, new side effects can appear months after finishing treatment.

Most people have mild side effects. Side effects are likely to be more severe if you are having higher doses or a combination of checkpoint inhibitor drugs, or if you are having immunotherapy with other cancer treatments.

Managing side effects

Because checkpoint inhibitors work differently from other cancer treatments, it's important to work closely with your treatment team to monitor any side effects and how the cancer responds.

Before starting checkpoint inhibitors, discuss the potential side effects with your cancer specialist. Ask about the side effects that should be reported, who to report them to, and who to contact after hours (see page 7). You can find out more about the side effects of specific checkpoint inhibitors at eviq.org.au.

You will usually have some tests to check that you are well enough to have immunotherapy before treatment begins. Throughout treatment, you will have regular blood tests, and the team will ask you questions to check for early signs of side effects. New side effects can appear months after having immunotherapy, so ask your cancer specialist how long you need to keep watching for side effects.



Let your treatment team know about any over-the-counter medicines, vitamins, supplements or herbal therapies you are thinking about using. Also, let them know if you have been prescribed any antibiotics or steroids. Some may affect how the checkpoint inhibitors work or make side effects worse.

Common and rare side effects of checkpoint inhibitors

Checkpoint inhibitors trigger an immune response that can lead to redness, swelling or pain (inflammation) anywhere in the body. The diagram below shows examples of common and rare side effects. The side effects you have will depend on the drug and how your body responds. While some people have serious side effects, others have just 1-2 mild issues. Although there are many possible side effects linked to checkpoint inhibitors, it's uncommon to get more than a few.

Common side effects

Fatigue

tiredness that does not go away with rest; caused by inflammation throughout your body

Dry eyes

from inflammation of the eyes or tear glands

Changes in weight and body temperature

inflammation can make the thyroid produce too much thyroid hormone (hyperthyroidism, leading to weight loss and feeling warm) or not enough (hypothyroidism, leading to weight gain and feeling cold)

Skin rash and itching

from dermatitis, which makes skin red, bumpy and itchy

Diarrhoea, abdominal pain and bloating

from inflammation of the bowel (colitis)

Joint pain

from inflammation of the joints (arthralgia), especially if you already have arthritis or a similar condition

Rare side effects

Headache or blurred vision

from inflammation of the pituitary gland (hypophysitis) or the membranes around the brain and spinal cord (meningitis)

Breathlessness, coughing, fainting or chest pain

from inflammation of the lungs or heart – rare but serious

Yellowing of the eyes, severe abdominal pain and dark urine

from inflammation of the liver (hepatitis)

Excessive thirst or urination

from inflammation of the pancreas affecting how much insulin it makes

Reduced urination or blood in the urine

could indicate problems in the kidneys – very rare but serious

Muscle pain

from inflammation of the muscles (myositis)

Confusion, seizures

from nerve problems – very rare but serious



Other rare side effects can occur, and some can be life-threatening. Let your treatment team know about any new or worsening side effects during or after treatment (see page 7). Do not try to treat them yourself. Most checkpoint inhibitor side effects can be managed and reversed if they are reported early.

Reporting side effects

Side effects can be better managed if reported early. It's important to let your cancer treatment team know about new or worsening symptoms, even if they seem minor or you're not sure if they are related to your treatment. If left untreated, side effects can become serious and may even be life-threatening.

Sometimes it can be tricky to know whether your symptoms are related to the cancer or the treatment. Ask your cancer treatment team about this.

Because checkpoint inhibitor therapy is a newer cancer treatment, some health professionals, including general practitioners (GPs), may not yet be familiar with the side effects. Your team may give you a card with information about your treatment and potential side effects. You can show this card to other health professionals you see and ask them to consult with your cancer specialist.

Do not start any new medicines, including probiotics, steroids, herbal therapies, or over-the-counter medicines, until you talk to your cancer specialist. If you become unwell, even years later, it is important to tell any health professionals you see that you have had immunotherapy.

Treating side effects

Your doctor will talk to you about how to manage mild to moderate side effects. For example, you may be given a moisturising cream to treat a skin rash. Moderate to severe side effects are often managed by pausing the checkpoint inhibitor and starting on steroid tablets, such as prednisolone.

In some cases, checkpoint inhibitors may be stopped until the side effects are better controlled. You may need to stay in hospital and/or have intravenous steroids or other medicines.

If side effects become severe, you may have to stop checkpoint inhibitor therapy permanently. Even so, you may continue to benefit from the therapy that you have already received because it may have "trained" your immune system to recognise cancer cells.

Although there is a risk of severe side effects, many people experience only mild side effects.



If you have had checkpoint inhibitor therapy, it's important to speak with your cancer specialist before having vaccinations, including for flu or COVID-19.

How will I know whether the checkpoint inhibitor is working?

You will have regular check-ups with your cancer specialist, blood tests and different types of scans to check whether the cancer has responded to the treatment. It may take some time to know if immunotherapy has worked because people often have a delayed response. In some cases, the cancer may appear to get worse before improving.

You may wonder whether having side effects means the checkpoint inhibitor is working. Side effects are a sign that the treatment is affecting your immune system in some way, but this may or may not mean the treatment is affecting the cancer.

A good response from checkpoint inhibitors will make the cancer shrink or disappear. In some cases, the cancer remains stable, which means it does not grow but also does not shrink or disappear. People with stable disease often continue to have a good quality of life.

What if the checkpoint inhibitor therapy doesn't work?

Unfortunately, checkpoint inhibitors do not work for everyone. Some cancers will not respond to the treatment at all, or the cancer cells can become resistant to the treatment even if it works at first. This can be very disappointing, but your cancer specialist will help you explore other treatment options if this happens.

How do I get checkpoint inhibitors?

Ask your cancer specialist if a checkpoint inhibitor drug would be a suitable treatment for you and whether it is reimbursed through the PBS for your type and stage of cancer (see page 4).

Checkpoint inhibitors may be available through clinical trials. Ask your treatment team about this.

► See our *Understanding Clinical Trials and Research* booklet.

Question checklist

It is important to ask your specialist questions, especially if you feel confused or uncertain about your treatment. You may want to make a list of your questions before your appointments and include some of the questions below.

- Is immunotherapy available as part of my treatment plan?
- How do I find out about clinical trials? Are there any nearby that might be right for me?
- Which immunotherapy drug are you recommending? Does it have different names?
- What percentage of people with this type of cancer respond to immunotherapy?
- How often have you prescribed this treatment? Has it worked well for your other patients?
- What do you expect the immunotherapy to do to the cancer? Will it be my only treatment?
- How much will immunotherapy cost? Is there any way to reduce the cost if I can't afford it?
- How often will I have immunotherapy?
- How long will I have treatment?
- Where will I have treatment?
- What side effects should I watch out for or report?
- Am I likely to get all of the side effects on the list?
- Who do I contact if I get side effects?
- How can side effects be managed?
- While I am having immunotherapy, can I take other medicines (including over-the-counter medicines) or supplements?
- Can I have the flu, COVID-19 or other vaccines?
- Can I use complementary therapies while I am on this treatment?
- How will I know if the treatment is working?
- Can diet and exercise assist with the success of the immunotherapy?

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Cancer Council acknowledges Traditional Custodians of Country throughout Australia and recognises the continuing connection to lands, waters and communities. We pay our respects to Aboriginal and Torres Strait Islander cultures and to Elders past, present and emerging.

Where to get help and information

Call Cancer Connect on 13 11 20 or visit the website for more information and support. Qualified professionals can listen to your concerns, put you in touch with services and send you our free booklets. You can also visit your local Cancer Council website.

Cancer Connect	cancerconnect.org.au
ACT	actcancer.org
NSW	cancercouncil.com.au
NT	cancer.org.au/nt
QLD	cancerqld.org.au
SA	cancersa.org.au
TAS	cancer.org.au/tas
VIC	cancervic.org.au
WA	cancerwa.asn.au
Australia	cancer.org.au

Other useful websites

You can find many useful resources online, but not all websites are reliable. These websites are good sources of support and information.

Cancer Council Online Community	cancercouncil.com.au/OC
Cancer Council podcasts	cancercouncil.com.au/podcasts
Australian Cancer Trials	australiancancertrials.gov.au
eviQ (cancer treatment information)	eviq.org.au
Peter MacCallum Cancer Centre	petermac.org (search for "immunotherapy videos")

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Note to reader

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