

TIME TO TALK
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IMMUNE CHECKPOINT INHIBITORS

HOW IMMUNE CHECKPOINT INHIBITORS WORK AND WHAT TO EXPECT

Chemotherapy works by trying to poison rapidly dividing cancer cells in the body.

Immune checkpoint inhibitors work in a different way. They use your body's own immune system, which protects you from infections, to treat cancer. These immune checkpoint inhibitors are also called *immunotherapy*.

Your immune system is made up of specialized immune cells, called T cells, that ignore normal cells (**Figure 1**) but recognize and kill harmful cells like viruses and bacteria (**Figure 2**). The T cells know the difference between a normal cell and a harmful invader because the body places checkpoints in front of normal cells.

You can think of these checkpoints as stop signs that tell the immune system *not* to destroy a cell (Figure 1).

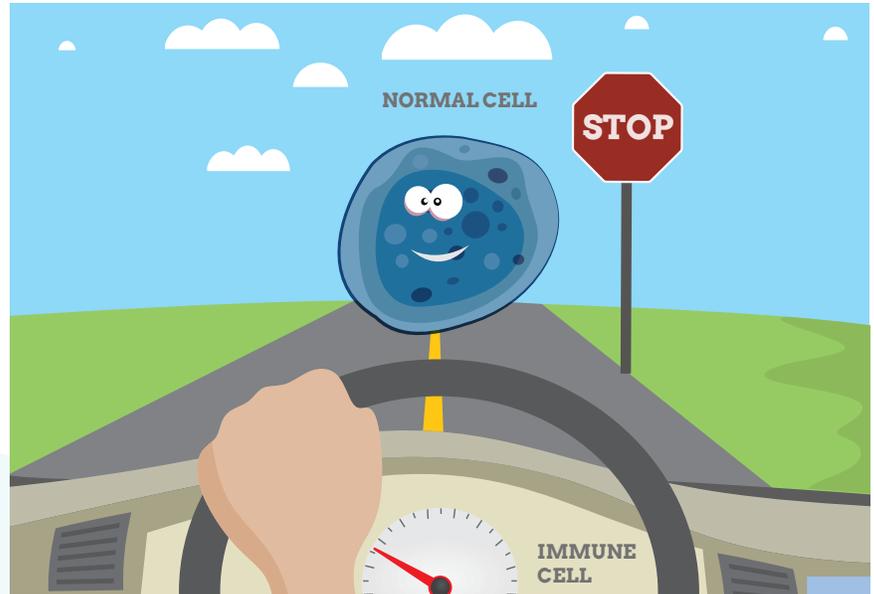


Figure 1. Immune cells ignore the body's normal cells.

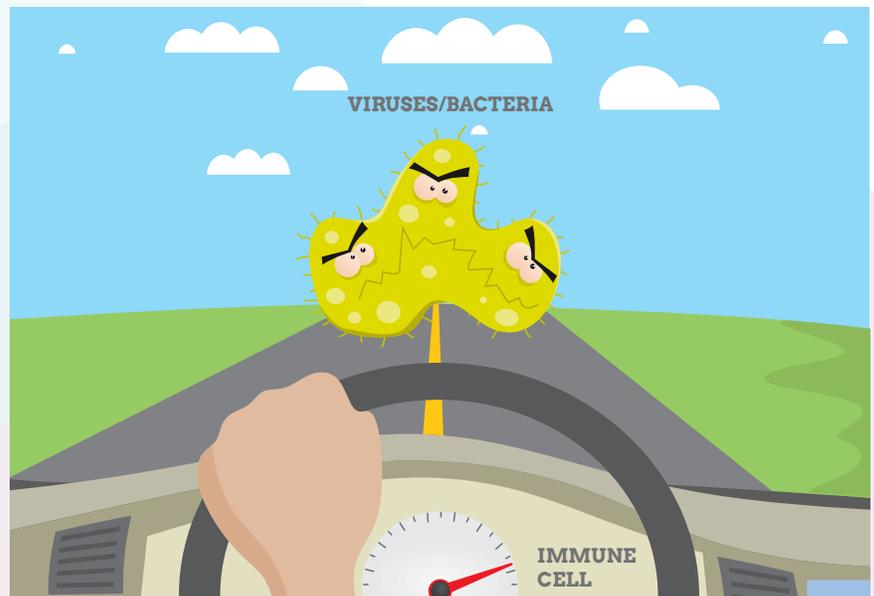


Figure 2. Immune cells recognize and kill harmful cells.

How Do Cancer Cells Escape Attack by the Immune System?

Normally, your body uses checkpoints to prevent immune cells from attacking normal cells and to keep them focused on the “bad guys,” like viruses and bacteria.

Cancer cells steal these stop signs and use them to avoid being destroyed by the immune system. When the cancer cell has a stop sign in front of it, the immune system won't attack it (**Figure 3**).

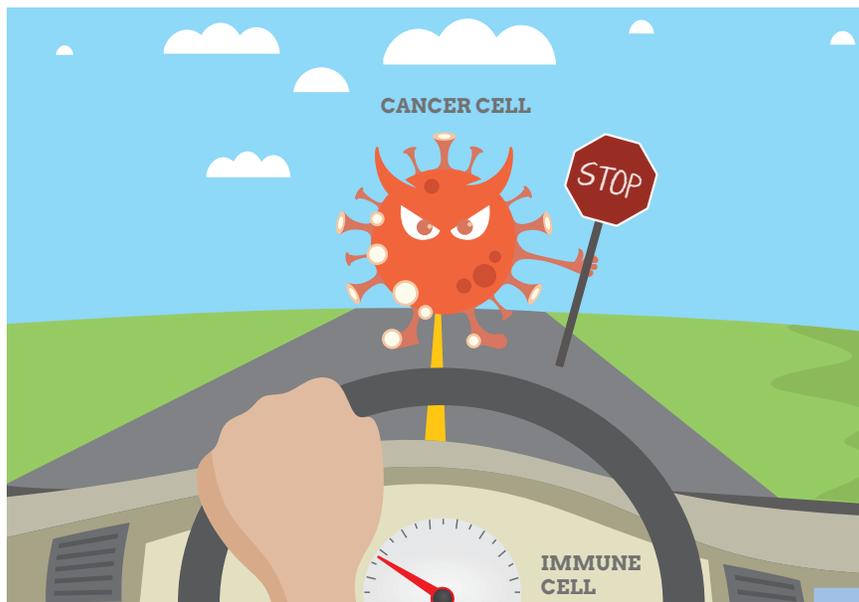


Figure 3. Cancer cells try to avoid being attacked by the body's immune cells.

How Do Immune Checkpoint Inhibitors Work to Kill Cancer?

Immune checkpoint inhibitors act like traffic controllers. They cover up the stop sign that the cancer is holding and hold up a sign saying “Go!” They allow the immune system to recognize the cancer cell as another “bad guy” that must be destroyed (**Figure 4**).

Available cancer drugs block three different checkpoints in the body: CTLA-4, PD1, and PD-L1. Several drugs can be used together to block different checkpoints and make sure that the immune system gets the signal to attack the cancer cells.



Figure 4. The checkpoint inhibitor stops the cancer cell from its effort to avoid being attacked by the immune cell.

What Causes Side Effects from Immune Checkpoint Inhibitors?

Just like different drivers of a car, each person's immune system reacts differently to these checkpoints or stop signs. When some people are given immunotherapy, their immune cells may ignore the stop signs in front of normal cells, almost as if the driver of the car has a foot on the gas pedal (**Figure 5**). The immune system traveling at a high speed can damage normal cells by mistake. This damage, called *auto-immune side effects*, is caused by a person's own immune system. When the side effects are recognized early, they can be treated with medications (such as steroids) that slow the immune cells down again, like decreasing the speed of a car.

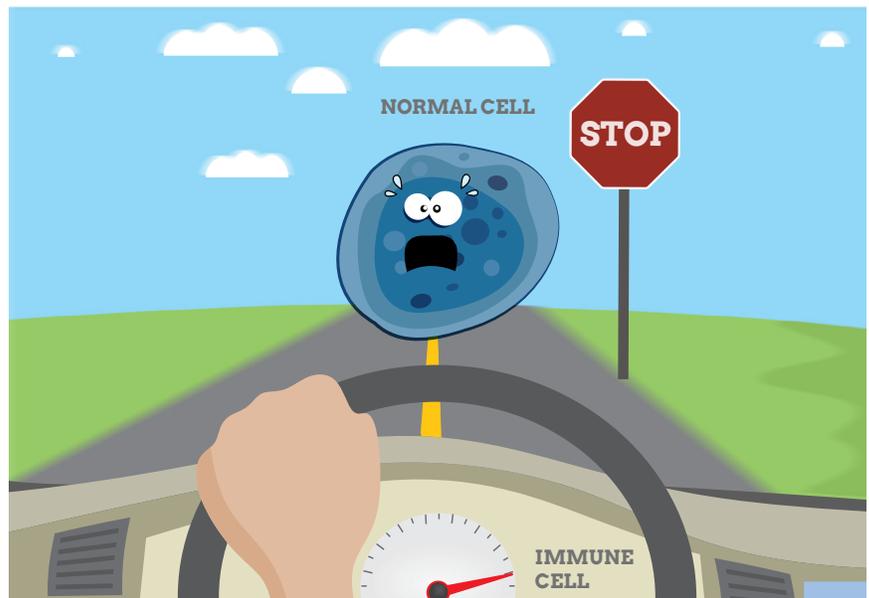


Figure 5. Some people's immune cells can react to the checkpoint inhibitors by damaging the normal cells.

What Can I Expect During Treatment?

What?

- Your immunotherapy can be given alone, with another immunotherapy, or with other cancer drugs.
- You will have blood tests and possibly other physical tests before you start your immunotherapy.
- You will have blood tests before each infusion of medication to make sure that you are not having any side effects.

Where?

- You may receive immunotherapy in a doctor's office, in a clinic, or in the hospital.

Who?

- A nurse or another trained healthcare professional will give you this therapy.
- You will meet with someone from your care team regularly to discuss how you are feeling, to make sure you are not having side effects, and to make sure your cancer is responding to the treatment.

When?

- Immunotherapy can be given every 2, 3, 4, or even 6 weeks, depending on the therapy and type of cancer being treated.

How?

- You will receive this medication through a vein in your arm or through a port-a-cath, a device that is placed under the skin near your collarbone.
- Medications may be given before the infusion to reduce side effects.
- Single immunotherapy infusions take 30–90 minutes to complete. If immunotherapy is combined with other cancer drugs, the infusion will take longer.



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SIDE EFFECTS OF IMMUNE CHECKPOINT INHIBITORS

Because immune checkpoint inhibitors (or immunotherapy) work to increase the ability of your own immune system to kill cancer cells, the side effects are different from those that may happen with chemotherapy drugs. Immunotherapy generally does not cause significant nausea or affect blood cell counts as sometimes happens with chemotherapy medications.

After the infusion of the immunotherapy drug, you may feel a little tired or achy for the next few days as your immune system starts to ramp up its attack on the cancer cells.

Sometimes the immunotherapy drug can cause the immune system to get overexcited. In these rare cases, immune cells can start to attack a normal part of your body rather than focusing on the cancer. This attack causes *auto-immune side effects*. If they are left untreated, the immune system can damage important organs and tissues in the body.

Because your immune system is present throughout your body, auto-immune side effects from immunotherapy can affect many parts of your body (**Figure 1**). Auto-immune side effects can happen even in areas where no cancer is present.

Auto-immune side effects can occur at any time during your treatment, even after you have been taking the cancer drug for months or years. It is important to pay close attention to your body to make sure you are not having any new, unexplained symptoms or symptoms that are getting worse. **Table 1** lists some symptoms you may notice in different parts of your body and when during treatment they may be more likely to occur.

Symptom Tracking

You may want to schedule a time each week to ask yourself whether you have noticed any new symptoms. Write them down so you can tell your healthcare provider about them. You can use this list of questions:

- How is my energy level?
- Do I have a new cough? Is my breathing the same as it was before I started taking the immunotherapy drug?
- Are my bowel movements normal (for me), or have I seen any changes?
- Do I have any new rashes on my body?
- Do I have pain anywhere that is not normal for me?

If you are having any new symptoms that bother you a lot or seem serious, always contact your healthcare team.

IMMUNE CHECKPOINT INHIBITORS

QUESTIONS TO ASK MY HEALTHCARE TEAM ABOUT IMMUNE CHECKPOINT INHIBITORS

Every person is different, and your cancer treatment plan will be designed especially for you. You can use these questions to help you discuss immune checkpoint inhibitors (immunotherapy) with your healthcare team.

About My Treatment

I am being treated for _____

The therapy (or therapies) I am receiving: _____

General Questions

- How is immunotherapy different from chemotherapy?
- How is immunotherapy given? How often? How long will each treatment take? Is a hospital stay required?
- Will I need someone to drive me to and from immunotherapy treatments? Can someone stay with me during my treatment?
- How long does it take for immunotherapy to work to treat my cancer?
- What tests will I need before and during my immunotherapy treatment?
- How often do I need to see my healthcare team while I am receiving immunotherapy?
- Will I be able to work while I am receiving immunotherapy?
- Will I be able to be around other people while I am receiving immunotherapy?
- Does my insurance cover the cost of my treatment? What resources are available to help with the cost of treatment?

Questions About Other Medications and Immunotherapy

- Do I need to take any medications before receiving immunotherapy?
- How will immunotherapy interact with my other prescription, over-the-counter, and herbal medications? Are there any medicines I should *not* take while I am receiving immunotherapy?
- Can I get vaccines while I am receiving immunotherapy?

Questions About Side Effects

- What side effects are common? What are some rare side effects I should know about?
- Do I have any risk factors that would put me at a higher risk of side effects from immunotherapy?
- When should I call my healthcare team about side effects? Which person should I call? When should I go to the emergency room?
- If I experience side effects from immunotherapy, what information does my healthcare team need to know?
- Are there medications I need to take while I am receiving immunotherapy to lessen side effects?
- If I do experience a side effect, what will happen to my treatment? Will I have to stop the immunotherapy?

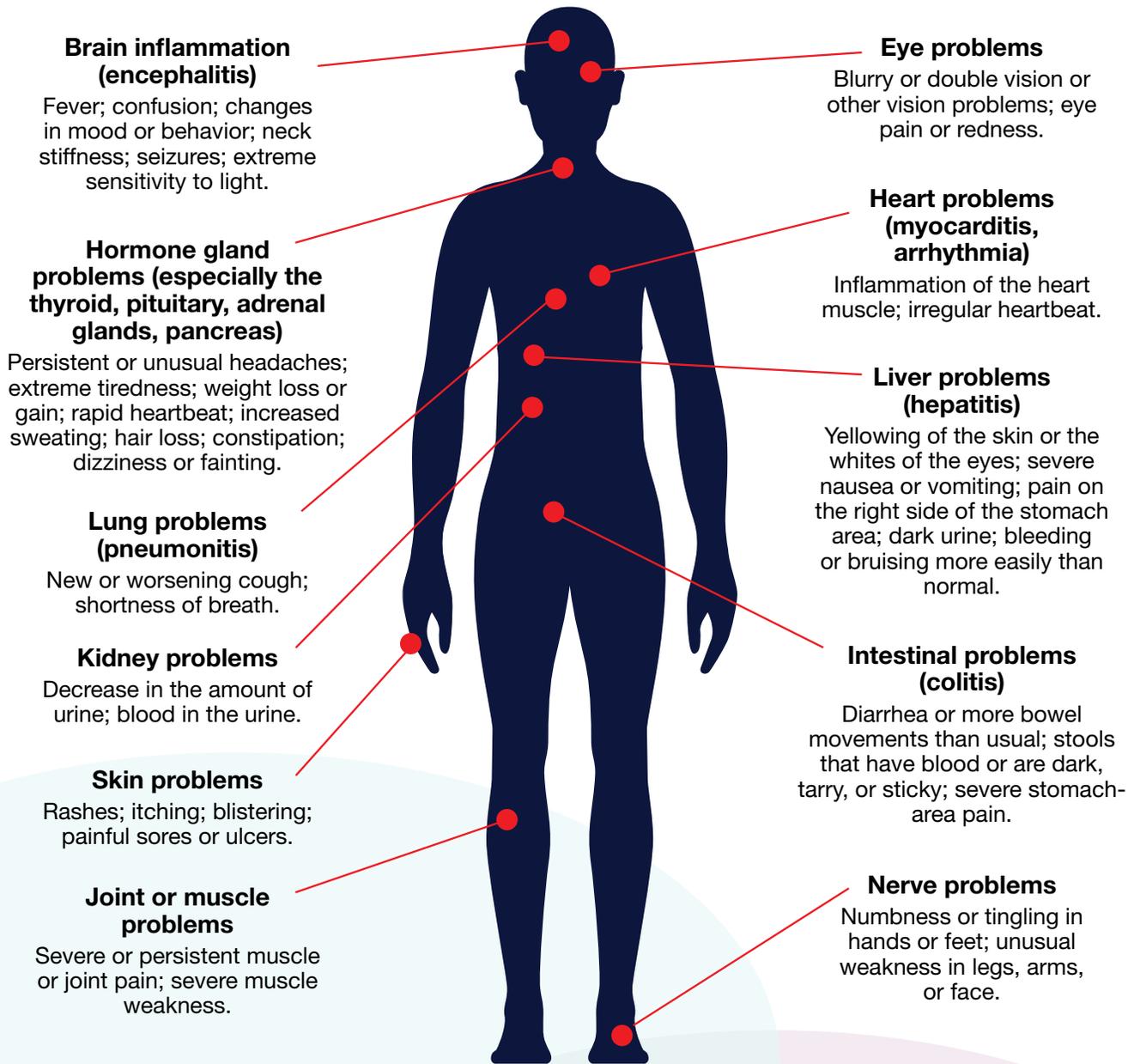


Figure 1. Auto-immune side effects may affect many parts of the body.

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Table 1. Symptoms of Possible Side Effects from Immunotherapy

	Part of Body Affected by Side Effect	When the Side Effect May Start to Occur	What You May Feel or See
More common symptoms	Gastrointestinal (GI) tract Most commonly occurs in the colon	Early in treatment (after 1 dose)	Diarrhea Blood in your stools or dark, tarry stools Severe abdominal pain or cramping Nausea or vomiting
	Skin Can happen anywhere on the body	Early in treatment (after 1 dose)	Rash Itching Lightening of skin Blisters or ulcers
	Hormone glands Most common in thyroid and pituitary glands	Mid-treatment (after 2 doses)	Excessive sleepiness Weight gain or weight loss Changes in mood or behavior Hair loss Feeling cold Constipation Excessive thirst or increased urination
Less common symptoms	Lungs	Mid-treatment (after 2 doses)	Shortness of breath New or worsening cough Chest pain
	Liver	Mid-treatment (after 2 doses)	Yellowing skin or eyes Dark urine Right-sided stomach pain
	Muscles and nerves Any muscle or nerve can be affected.	Late in treatment (after 3 or more doses)	Muscles: general weakness or fatigue Nerves: numbness or tingling
	Kidneys	Late in treatment (after 3 or more doses)	Decreased urination or dark urine Pain in the middle of the back Swelling in the ankles
	Brain and eyes	Late in treatment (after 3 or more doses)	Headache Confusion Changes in vision Excessive sleepiness or fatigue
	Heart	Late in treatment (after 3 or more doses)	Swelling in the ankles Chest pain Shortness of breath or difficulty breathing

Management of Side Effects

These side effects can generally be treated with drugs, such as corticosteroids, that calm down the overexcited immune system.

If you are having a side effect from immunotherapy, **it is very important to receive treatment with immune-suppressing drugs as soon as possible** to prevent severe or permanent damage to organs and tissues.

You should call your healthcare team to report any new or worsening symptom, large or small, so they can help you determine whether treatment for an autoimmune side effect is needed.

Side effects are treated differently depending on how severe they are. Some side effects can be managed during a clinic visit with your healthcare team. More serious side effects may require that you go to the hospital.

Figure 2 shows the way that treatment may change as the side effects become more serious.

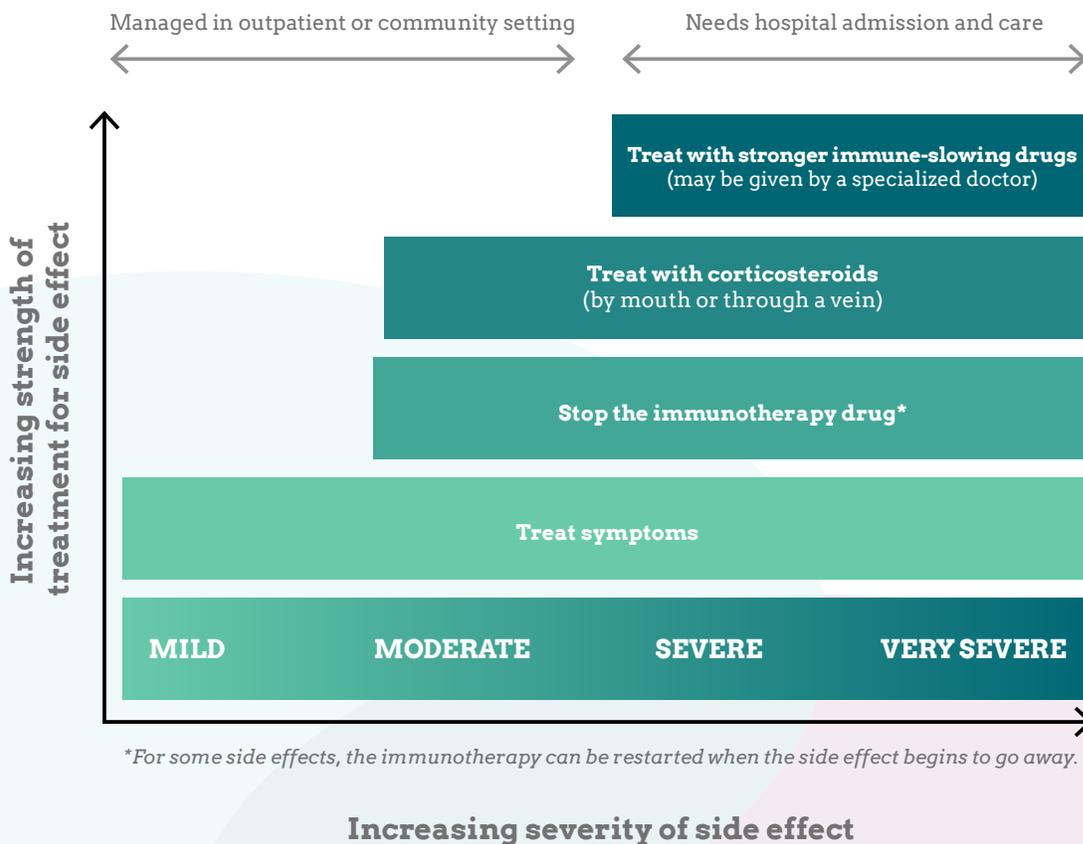


Figure 2. Changes in treatment depend on how severe the side effects are.

If you have an auto-immune side effect, the following steps may be taken:

- You may be given treatments that control your symptoms without interfering with the immune system. Examples:
 - creams to soothe an itchy rash
 - medicines to lessen diarrhea
 - medicines that bring your hormone levels back to normal
- Treatment with the immunotherapy drug may be stopped for a short time, or completely.
- You may be treated with corticosteroids (for example, prednisone, dexamethasone, or methylprednisolone) to slow down the immune system. These can be given in creams (such as for a rash), taken as pills by mouth, or given through the vein.
- You may be treated with other immune-suppressing drugs. If additional immune-suppressing drugs are needed, your healthcare team may suggest that you visit a specialist who can help decide on the best medicine for you.

Self-Care

It is very important that you take care of yourself while you are receiving immunotherapy. Here are some tips:

- Eat a healthy, well-balanced diet.
- Exercise frequently, as approved by your doctor.
- Choose a family member or friend to be your caregiver at home. Talk with this person about your symptoms, feelings, and any concerns you have about your treatment. Don't be afraid to ask for help if you need it. Your caregiver can help you feel supported when you have concerns to discuss with the healthcare team.
- Talk to your healthcare team about any new symptoms, large or small. Don't wait until your next appointment if you notice that you are having a new symptom, even if you aren't sure that it was caused by the immunotherapy drug.

Don't wait! Remember that treating auto-immune side effects *early* will help prevent them from becoming more serious.

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RESOURCES FOR PATIENTS WITH CANCER

Table 1. Financial Resources for Patients Receiving Immunotherapy

Organization or Program	Phone Number	Website	Immunotherapy Agent generic name (Trade name)
AstraZeneca Access 360	844.ASK.A360 (800.275.2360)	www.MyAccess360.com	durvalumab (Imfinzi)
Bristol-Myers Squibb	800.861.0048	www.bmsaccesssupport.bmscustomerconnect.com/patient/financial-support	ipilimumab (Yervoy) nivolumab (Opdivo)
Cover One	844.8COVER1 (844.826.8371)	www.coverone.com/en/home.html	avelumab (Bavencio)
Genentech Access Solutions	866.422.2377	www.genentech-access.com/patient.html	atezolizumab (Tecentriq)
Libtayo Surround	877.LIBTAYO (877.542.8296)	www.libtayo.com/support	cemiplimab (Libtayo)
Merck Access Programs	855.257.3932	www.merckaccessprogram.keytruda.com/hcc/	pembrolizumab (Keytruda)

Table 2. Other Resources for Patients with Cancer

Organization	Phone Number	Website	Services Provided
Financial Resources: General			
American Cancer Society	800.277.2345	www.cancer.org	Financial tools
Brenda Mehling Cancer Fund		https://www.youngsurvival.org/directory/young-adult/brenda-mehling-cancer-fund	Financial assistance (ages 18–40 years)
Bringing Hope Home	484.580.8395	bringinghopehome.org	Financial assistance

Table 2. Other Resources for Patients with Cancer (continued)

Organization	Phone Number	Website	Services Provided
Cancer Financial Assistance Coalition		www.cancerfac.org	Financial assistance
Cancer Warrior Inc.	323.578.5083	www.cancerwarriorinc.org	Financial assistance
Family Reach Foundation	Boston office: 857.233.2764 New Jersey office: 973.394.1411	familyreach.org	Financial assistance and planning
HealthWell Foundation	800.675.8416	www.healthwellfoundation.org	Financial assistance (medical)
Life Beyond Cancer Foundation		www.needhelp-payingbills.com/html/life_beyond_cancer_foundation.html	Financial assistance
Patient Access Network Foundation	866.316.7263	panfoundation.org/index.php/en	Financial assistance
Patient Advocate Foundation	800.532.5274	www.patientadvocate.org	Financial assistance, resource assistance locator
Patient Services Inc.	800.366.7741	www.patientservicesinc.org	Financial assistance
Team Continuum	845.200.7094	www.teamcontinuum.net	Financial assistance (nonmedical needs)
The C.H.A.I.N. Fund	203. 691.5955	https://www.uacommunitycancerconnections.org/content/chain-fund-inc	Financial assistance
Financial Resources: Prescriptions and Medications			
Good Days	877.968.7233	www.mygooddays.org	Financial resources
Medicine Assistance Tool	888.477.2669	medicineassistancetool.org	Resource assistance locator: medications, free and low-cost clinics
NeedyMeds	800.503.6987	www.needymeds.org	Resource assistance locator: medication, healthcare costs
RxAssist		www.rxassist.org	Patient assistance program directory
RxHope		www.rxhope.com	Prescription and medication assistance
RxOutreach	800.796.1234	rxoutreach.org	Prescription assistance

Table 2. Other Resources for Patients with Cancer (continued)

Organization	Phone Number	Website	Services Provided
Together Rx Access		http://trxaccess.org	Prescription assistance
Housing and Lodging			
Cleaning for a Reason	877.337.3348	cleaningforareason.org	Cleaning services
Fisher House	888.294.8560	www.fisherhouse.org	Housing and lodging (for military and veteran families when a family member is in the hospital)
Healthcare Hospitality Network	800.542.9730	www.hhnetwork.org	Housing and lodging
Hope Lodge	800.227.2345	www.cancer.org/treatment/support.programs.and.services/patient.lodging/hope.lodge.html	Housing and lodging
Hospitality Homes	888.595.4678	hosp.org	Housing and lodging
Joe's House	877.563.7468	www.joeshouse.org	Housing and lodging
Multipurpose and Other Resources			
Association of Community Cancer Centers: Patient Assistance and Reimbursement Guide		www.accc-cancer.org/home/learn/publications/patient-assistance-and-reimbursement-guide	Guide to receiving financial assistance for a variety of cancer medications and navigating the insurance process
BenefitsCheckUp		www.benefitscheckup.org	Needs of the elderly
Cancer Survivors' Fund	281.437.7142	www.cancersurvivorsfund.org	Needs of young cancer survivors: scholarships, prosthetic limbs, emotional support
CancerCare	800.813.4673	www.cancercare.org	Counseling, support groups, financial assistance
Livestrong Foundation	877.236.8820	www.livestrong.org	Financial assistance, assistance with fertility, insurance, care and support
National Organization for Rare Disorders	203.744.0100	rarediseases.org	Patient assistance, financial assistance, resources for patients and caregivers

Table 2. Other Resources for Patients with Cancer (continued)

Organization	Phone Number	Website	Services Provided
Social Security Disability Resource Center		www.ssdrc.com	Assistance with the disability filing process
State Health Insurance Assistance Programs		www.medicare.gov/Contacts	Medicare: state-specific contact information
Stupid Cancer		stupidcancer.org	Financial and legal assistance, fertility assistance, insurance needs for young adults
Verna's Purse	Florida: 888.953.9669 Minnesota: 888.489.8944 Nevada: 888.831.2765 Texas: 888.350.3247	www.reprotech.com/financial-assistance.html	Fertility preservation
Zichron Shlome Refuah Fund	718.438.9355	www.zsrf.org/services.php	Medical expenses, wigs, vitamin therapy, transportation, housekeeping, housing assistance, insurance



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WALLET CARD

This wallet card will help you share information with other healthcare providers about your immunotherapy. Fill out the information requested (ask your cancer team if you need help), print out the card, and carry it in your wallet. You should show the card to members of your healthcare team who are not treating your cancer, like an emergency room staff member or your primary care provider, so they know to look out for special issues related to your immunotherapy.

HEALTHCARE PROVIDER ALERT: IMMUNOTHERAPY PATIENT

Patient's Name: _____

Cancer Type: _____

Immunotherapy Drug: _____

Start Date of Immunotherapy: _____

Note: Immunotherapy agents are not chemotherapy drugs. Immune-related side effects are possible at any point in treatment. Please contact the oncology team to discuss concerns about treatment.

HEALTHCARE PROVIDER ALERT: IMMUNOTHERAPY PATIENT

Cancer Physician's Name: _____

Office Phone Number: _____

After-Hours Phone Number: _____

Immune-related side effects may present as rash, diarrhea, cough, fatigue, headaches, cough, shortness of breath, or muscle weakness. They may occur during or after treatment. Side effects may require treatment with steroids. Please consult the oncology team before treating side effects or changing cancer-related treatment.