TECVAYLI®
(teclistamab-cqyv) Injection for subcutaneous use
10 mg/mL and 90 mg/mL

Your guide to **TECVAYLI®**

Simple moments, meaningful outcomes

For the 62% of people who responded to TECVAYLI® in the clinical trial

BRIGHT
Possibilities

TECVAYLI® is the first treatment of its kind for multiple myeloma—it's called a bispecific antibody, and it works by binding to both multiple myeloma cells as well as T-cells to help your immune system recognize the multiple myeloma cells and destroy them.

What is TECVAYLI® (teclistamab-cqyv)?
TECVAYLI® is a prescription medicine to treat adults with multiple myeloma who:

- have already received at least 4 treatment regimens, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody to treat their multiple myeloma,
  and
- their cancer has come back or did not respond to prior treatment

TECVAYLI® was approved based on patient responses. There are ongoing studies to confirm the clinical benefit of TECVAYLI®.

It is not known if TECVAYLI® is safe and effective in children.

IMPORTANT SAFETY INFORMATION
What is the most important information I should know about TECVAYLI®?

TECVAYLI® may cause side effects that are serious, life-threatening, or lead to death, including Cytokine Release Syndrome (CRS) and neurologic problems.

Call your healthcare provider right away if you develop any of the signs or symptoms of CRS or neurologic problems listed below at any time during your treatment with TECVAYLI®:

Cytokine Release Syndrome (CRS). Signs and symptoms of CRS may include:

- fever (100.4°F or higher)
- difficulty breathing
- chills
- dizziness or lightheadedness
- fast heartbeat
- feeling anxious
- confusion or restlessness
- headache
- increased liver enzymes in your blood

Please read full Important Safety Information on pages 8-11, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

You have many reasons to stay hopeful—there are still options for you after you relapse

When you have multiple myeloma, the medicines that were working before can stop working, and you can experience relapse. When you try a medicine but don't get a response, this means your multiple myeloma is refractory to that medicine.

There are still ways to fight relapsed or refractory multiple myeloma, including trying a different medicine from the kinds you have already tried.

Please read full Important Safety Information on pages 8-11, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

Is it time for TECVAYLI®?

If your multiple myeloma is refractory or relapsed, ask your healthcare provider if TECVAYLI® is right for you

TECVAYLI® is for adults with multiple myeloma whose cancer has come back or did not respond to treatment after having received at least 4 prior treatment regimens, including:

- a proteasome inhibitor
- an immunomodulatory agent
- an anti-CD38 monoclonal antibody

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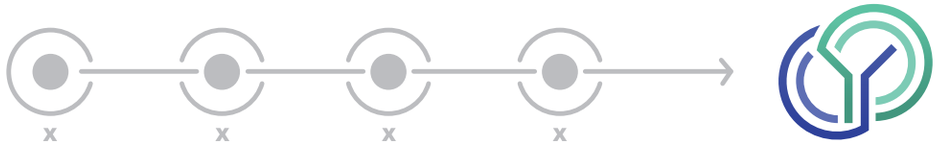

IMPORTANT SAFETY INFORMATION (cont'd)

What is the most important information I should know about TECVAYLI®? (cont'd)

Neurologic problems. Symptoms of neurologic problems with TECVAYLI® include:

- headache
- jerking movements
- rigid muscles
- feeling restless
- numbness and tingling (feeling like "pins and needles")
- confusion
- trouble speaking
- muscle spasms
- tremor
- double vision
- changes in your handwriting
- problems walking
- muscle weakness in your body or face
- hearing loss
- burning, throbbing, or stabbing pain

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If you're going through another relapse, it may be time to talk to your doctor about making a change

There are medicines for relapsed or refractory multiple myeloma that may be able to help manage your disease. Talk to your doctor to see if TECVAYLI® is right for you.

IMPORTANT SAFETY INFORMATION (cont'd)

What is the most important information I should know about TECVAYLI®? (cont'd)

- Due to the risk of CRS and neurologic symptoms, you should be hospitalized for 48 hours after all doses of TECVAYLI® that are part of the "step-up dosing schedule." The "step-up dosing schedule" is when you receive the first 2 doses of TECVAYLI®, which are called "step-up doses," and then you receive the first "treatment dose" of TECVAYLI®. After "step-up dose 1" of TECVAYLI®, the dose of TECVAYLI® is increased. After "step-up dose 2," the dose is increased again when you receive the first "treatment dose" of TECVAYLI®.
  - "Step-up dose 1" is given on day 1 of treatment. "Step-up dose 2" is usually given on day 4 of treatment. The first "treatment dose" is usually given on day 7 of treatment.
  - Your healthcare provider will decide when you will receive "step-up dose 2" and your first "treatment dose."
    - "Step-up dose 2" may be given between 2 to 4 days after "step-up dose 1," or up to 7 days after "step-up dose 1" if you have certain side effects with TECVAYLI®.
    - Your first "treatment dose" may be given between 2 to 4 days after "step-up dose 2," or up to 7 days after "step-up dose 2" if you have certain side effects with TECVAYLI®.
  - Your healthcare provider will decide the number of days to wait between your doses of TECVAYLI® as well as how many treatments you will receive.
  - If your dose of TECVAYLI® is delayed for any reason, you may need to repeat the "step-up dosing schedule" to receive TECVAYLI®.
  - Before each "step-up dose" and your first "treatment dose" of TECVAYLI®, you will receive medicines to help reduce your risk of CRS. Your healthcare provider will decide if you need to receive medicines to help reduce your risk of CRS with future doses.

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In this guide

Use this guide to learn more about TECVAYLI®.

TECVAYLI® (teclistamab-cqyv) Injection for subcutaneous use 10 mg/mL and 90 mg/mL

How TECVAYLI® works

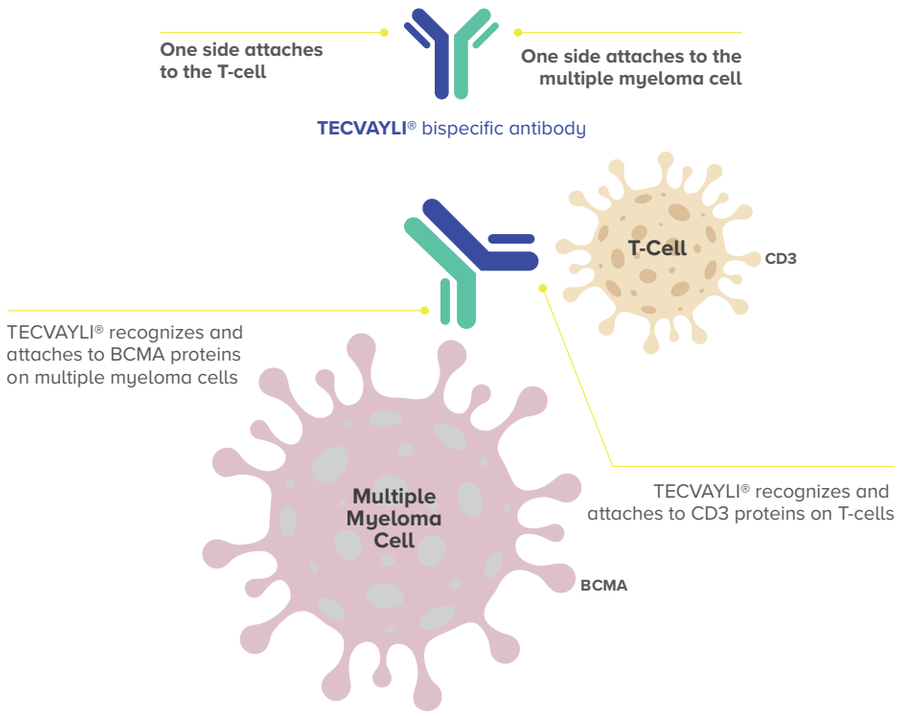
TECVAYLI®, a bispecific antibody, is the first treatment of its kind designed to fight multiple myeloma

TECVAYLI® works by helping your immune system locate the multiple myeloma cells in your body.

One side of TECVAYLI® binds to proteins called BCMA, which are found on multiple myeloma cells (as well as some healthy cells). The other side binds to proteins called CD3, which are found on your T-cells.

In doing so, TECVAYLI® is able to activate the T-cells in your immune system to destroy the multiple myeloma cells in the rest of your body.

TECVAYLI® is a kind of medicine called a bispecific antibody, which means that it attaches to 2 different cells



By binding to BCMA and CD3, TECVAYLI® helps the immune system recognize the multiple myeloma cell and destroy it.

TECVAYLI® is a different kind of therapy that may help you fight your disease.

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Results with TECVAYLI®

TECVAYLI® was studied in 110 adults, 78% of whom had already been on at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

More than half of adults saw results with TECVAYLI® in the clinical trial

62% of people in the clinical trial who took TECVAYLI® responded.

28% of people taking TECVAYLI® had a complete response or better to treatment. 29% of people taking TECVAYLI® had a very good partial response, and 5% had a partial response.

Median time to first response with TECVAYLI® was 1.2 months (response times ranged from 0.2 months to 5.5 months).

Talk to your doctor for more information about response.

BCMA, B-cell maturation antigen; CD3, cluster of differentiation 3; CD38, cluster of differentiation 38.

IMPORTANT SAFETY INFORMATION (cont'd)

What is the most important information I should know about TECVAYLI®? (cont'd)

- Your healthcare provider will monitor you for signs and symptoms of CRS and neurologic problems during treatment with TECVAYLI®, as well as other side effects, and treat you as needed.
- **Do not drive or operate heavy or dangerous machinery during and for 48 hours after your TECVAYLI® "step-up dosing schedule" is completed, or at any time during treatment with TECVAYLI® if you develop new neurologic symptoms until the symptoms go away.**

TECVAYLI® (teclistamab-cqyv) Injection for subcutaneous use
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What is TECVAYLI® (teclistamab-cqyv)?

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TECVAYLI® was approved based on patient responses. There are ongoing studies to confirm the clinical benefit of TECVAYLI®.

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IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TECVAYLI®?

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- chills
- dizziness or lightheadedness
- fast heartbeat
- feeling anxious
- confusion or restlessness
- headache
- increased liver enzymes in your blood

Neurologic problems. Symptoms of neurologic problems with TECVAYLI® include:

- headache
- jerking movements
- rigid muscles
- feeling restless
- numbness and tingling (feeling like “pins and needles”)
- confusion
- trouble speaking
- muscle spasms
- tremor
- double vision
- changes in your handwriting
- problems walking
- muscle weakness in your body or face
- hearing loss
- burning, throbbing, or stabbing pain

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  - “Step-up dose 1” is given on day 1 of treatment. “Step-up dose 2” is usually given on day 4 of treatment. The first “treatment dose” is usually given on day 7 of treatment.
  - Your healthcare provider will decide when you will receive “step-up dose 2” and your first “treatment dose.”
    - “Step-up dose 2” may be given between 2 to 4 days after “step-up dose 1,” or up to 7 days after “step-up dose 1” if you have certain side effects with TECVAYLI®.
    - Your first “treatment dose” may be given between 2 to 4 days after “step-up dose 2,” or up to 7 days after “step-up dose 2” if you have certain side effects with TECVAYLI®.
  - Your healthcare provider will decide the number of days to wait between your doses of TECVAYLI® as well as how many treatments you will receive.
  - If your dose of TECVAYLI® is delayed for any reason, you may need to repeat the “step-up dosing schedule” to receive TECVAYLI®.
  - Before each “step-up dose” and your first “treatment dose” of TECVAYLI®, you will receive medicines to help reduce your risk of CRS. Your healthcare provider will decide if you need to receive medicines to help reduce your risk of CRS with future doses.
- Your healthcare provider will monitor you for signs and symptoms of CRS and neurologic problems during treatment with TECVAYLI®, as well as other side effects, and treat you as needed.
- **Do not drive or operate heavy or dangerous machinery during and for 48 hours after your TECVAYLI® “step-up dosing schedule” is completed, or at any time during treatment with TECVAYLI® if you develop new neurologic symptoms until the symptoms go away.**

TECVAYLI® is available only through the TECVAYLI® and TALVEY™ Risk Evaluation and Mitigation Strategy (REMS) due to the risk of CRS and neurologic problems.

You will receive a Patient Wallet Card from your healthcare provider. **Carry the Patient Wallet Card with you at all times and show it to all of your healthcare providers.** The Patient Wallet Card lists signs and symptoms of CRS and neurologic problems.

Get medical help right away if you develop any of the signs and symptoms listed on the Patient Wallet Card. You may need to be treated in a hospital.

Your care team will enroll in the REMS program and provide you with a Patient Wallet Card to carry with you.
You do not need to enroll in the REMS program.

- If you have any questions about TECVAYLI®, ask your healthcare provider.
- Your healthcare provider may temporarily stop or completely stop your treatment with TECVAYLI® if you develop CRS, neurologic problems, or any other side effects that are severe.

See **“What are the possible side effects of TECVAYLI®?”** for more information about side effects.

Before you receive TECVAYLI®, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection
- are pregnant or plan to become pregnant. TECVAYLI® may harm your unborn baby.
  - Your healthcare provider should do a pregnancy test before you start treatment with TECVAYLI®.
  - You should use effective birth control (contraception) during treatment and for 5 months after your last dose of TECVAYLI®.
  - Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with TECVAYLI®.
- are breastfeeding or plan to breastfeed. It is not known if TECVAYLI® passes into your breast milk. Do not breastfeed during treatment and for 5 months after your last dose of TECVAYLI®.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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How will I receive TECVAYLI®?

- TECVAYLI® will be given to you by your healthcare provider as an injection under your skin (subcutaneous injection), usually in your stomach area (abdomen). Your thigh or another area of your body may be injected.
- **See "What is the most important information I should know about TECVAYLI®?" at the beginning of this Important Safety Information for information about how you will receive TECVAYLI®.**

If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment. It is important for you to be monitored closely for side effects during treatment with TECVAYLI®.

What are the possible side effects of TECVAYLI®?

TECVAYLI® may cause serious side effects, including:

- See **"What is the most important information I should know about TECVAYLI®?"**
- **Liver problems**. TECVAYLI® can cause liver problems that may lead to death. Increased bilirubin and liver enzymes in your blood are common with TECVAYLI® and can also sometimes be severe. These increases in liver enzymes can happen with or without you also having CRS. Your healthcare provider will monitor you for these problems before you start and during treatment with TECVAYLI®. **Tell your healthcare provider if you develop any symptoms of a liver problem including:**
  - tiredness
  - loss of appetite
  - pain in your right upper stomach area (abdomen)
  - dark urine
  - yellowing of your skin or white part of your eyes
- **Infections**. Upper respiratory tract infections and pneumonia are common with TECVAYLI®. TECVAYLI® can cause bacterial and viral infections that are severe, life-threatening, or that may lead to death.
  - Your healthcare provider will monitor you for signs and symptoms of infection before and during treatment with TECVAYLI®.
  - Your healthcare provider may prescribe medicines for you to help prevent infections, and treat you as needed if you develop an infection during treatment with TECVAYLI®.
  - Tell your healthcare provider right away if you get a fever, chills, or any signs or symptoms of an infection.
- **Decreased white blood cell counts**. Decreased white blood cell counts are common with TECVAYLI® and can also be severe. Fever sometimes also happens with low white blood cell counts and may be a sign that you have an infection. Your healthcare provider will check your blood cell counts before you start and during treatment with TECVAYLI®, and treat you as needed.
- **Allergic reactions and injection site reactions**. TECVAYLI® can cause allergic reactions that can affect your whole body (systemic), and also cause injection site reactions.
  - Some people taking TECVAYLI® can develop symptoms of an allergic reaction that can affect their whole body and may include fever or a swollen tongue. **Get medical help right away if you develop symptoms of an allergic reaction during treatment with TECVAYLI®.**
  - Injection site reactions are common with TECVAYLI® and can include: redness, heat, swelling, bruising, bacterial skin infection (cellulitis), discomfort, blood collection under the skin at the injection site (hematoma), and rash. Tell your healthcare provider if you develop any severe injection site reactions.

Your healthcare provider may temporarily or permanently stop TECVAYLI® if you have any of the side effects listed above and they are severe.

Please read full Important Safety Information on pages 8-11, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

The most common side effects of TECVAYLI® include:

- fever
- pain in your joints and muscles, back and chest muscles, and in your arms and legs
- tiredness and weakness
- upper respiratory tract infections and pneumonia. See "Infections" above.
- nausea
- headache
- diarrhea

The most common severe abnormal lab test results with TECVAYLI® include: decreased white blood cells, red blood cells, and platelets.

These are not all the possible side effects of TECVAYLI®.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please read full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

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Step-up dosing may help reduce both the chance of getting CRS and the severity of it

TECVAYLI® activates your immune cells to help fight your disease. This activation can cause a serious or life-threatening side effect called Cytokine Release Syndrome (or CRS).

Your provider will give you premedication and use step-up dosing to decrease the likelihood and severity of CRS. Pretreatment medications may also be needed for doses given after a dose delay.

- Most instances of CRS happened during the first 3 doses
  - 42% of people taking TECVAYLI® experienced CRS after step-up dose 1, 35% after step-up dose 2, and 24% after the initial treatment dose (the third dose)
  - Less than 3% of people taking TECVAYLI® had a first occurrence of CRS after the third dose
- The median time to CRS occurring was 2 days (with a range of 1 to 6 days) after the most recent dose. The median amount of time that CRS lasted was 2 days (with a range of 1 to 9 days)

Your healthcare team may change your treatment plan if you experience side effects.

TECVAYLI® (teclistamab-cqyv) Injection for subcutaneous use 10 mg/mL and 90 mg/mL

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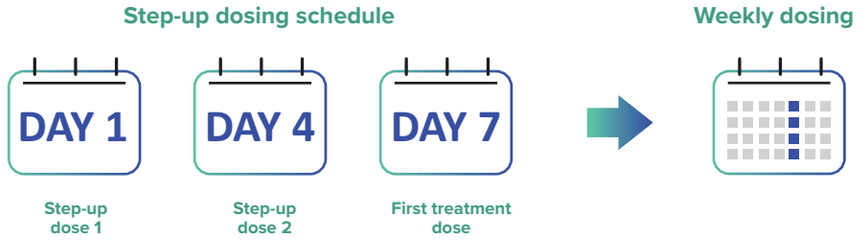
TECVAYLI® is a ready-to-use treatment

TECVAYLI® is given by a doctor or nurse as a **subcutaneous injection** under the skin, usually in your stomach area (abdomen), your thigh, or another area of your body.

TECVAYLI® starts with what is called "step-up" dosing

Step-up dosing is done with TECVAYLI® to reduce the chance of getting CRS and/or experiencing neurologic problems. The amount of TECVAYLI® you receive will be increased from the first to second dose, and then increased again from the second to third dose. The amount of TECVAYLI® you receive will be based on your body weight. The amount given for the third dose will be the same as your ongoing weekly dose. You should be hospitalized for 48 hours after each dose given to you during the step-up dosing schedule.

Step-up dosing may be administered in the hospital setting



Step-up dose 2 and/or the first treatment dose may be given between 2 to 4 days* after the previous step-up dose so your healthcare team can manage any side effects.

*But could be given up to 7 days after the previous step-up dose. Your healthcare provider will decide the number of days to wait between your doses of TECVAYLI®.

Things to keep in mind as you start TECVAYLI®

- Tell your doctor or healthcare provider about any medications you are currently taking, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements
- Before each step-up dose and your first treatment dose of TECVAYLI®, you will receive medicines to help reduce your risk and/or lessen the severity of a serious or life-threatening side effect known as CRS
- After your step-up doses, your healthcare provider will decide if you need to receive medicines to help reduce your risk of CRS with future doses
- You should be hospitalized for 48 hours after administration of all doses within the TECVAYLI® step-up dosing schedule

CRS, cytokine release syndrome.

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You may need to receive care at more than one treatment center as you start and continue TECVAYLI®

You should be admitted to the hospital when you start treatment with TECVAYLI®. This is where you should receive your step-up dosing schedule, so that you can be monitored for at least 48 hours after each dose to ensure you are tolerating the treatment. Once the step-up dosing schedule is complete, you will transition to receiving weekly doses of TECVAYLI®, which may be given at a different treatment facility in the outpatient setting.

Here are some tips to keep in mind during transitions in your care:

After an initial step-up dosing schedule, you will be given TECVAYLI® weekly thereafter, possibly at a different location. Your care team can help you set up these appointments, and you may want to consider scheduling the first one before you leave the hospital. It should take place one week after your first treatment dose.

Talk to your care team about when and where you will receive your initial step-up doses of TECVAYLI®, and where you will receive your ongoing weekly treatment doses. It is very important to have good communication with your care team. If there's anything you're unsure about, don't hesitate to ask.

To help you keep track of treatment, the *Getting Started with TECVAYLI®* brochure includes a section for you to jot down each time you're given a dose of TECVAYLI®.

It's also a good idea to keep track of how you're feeling each day so that you can discuss it with your care team to help them determine whether or not you are experiencing side effects. You may also want to save important contact numbers in your phone so that you can easily get in touch with your care team if/whenever necessary.

Remember to always carry your Patient Wallet Card so that you can be easily identified as someone receiving TECVAYLI®. You may also want to take a picture of it with your cellphone in the event that you misplace the card.

It's important to continue with the treatment plan your doctor has prescribed during transitions of care. This can help you make the most of your TECVAYLI® treatment.

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IMPORTANT SAFETY INFORMATION (cont'd)

What is the most important information I should know about TECVAYLI®? (cont'd)

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Before you receive TECVAYLI®, tell your healthcare provider about all of your medical conditions, including if you:
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A one-on-one support program designed for you

Once you and your doctor have decided that TECVAYLI® is right for you, *Janssen Compass*® is a free, personalized patient support program that can help you get started with your treatment and stay on track.

Your *Janssen Compass*® Care Navigator is just a phone call away! You can also call us at 844-628-1234, Monday through Friday, 8:30 AM – 8:30 PM ET.

Once you are enrolled, a dedicated Care Navigator can help you find the resources you need

Paying for TECVAYLI®

Explore options that may be available to help you save on potential out-of-pocket medication costs. Whether you have commercial insurance or government-funded coverage—or even no insurance at all—we can help you find programs that may help you pay for TECVAYLI®.

Learning About Your TECVAYLI® Treatment

A *Janssen Compass*® Care Navigator will support and guide you as you start and continue treatment by providing ongoing education about TECVAYLI®.

Staying Supported the Whole Way

While you're on TECVAYLI®, you will work with your *Janssen Compass*® Care Navigator to discover tips, strategies, and resources for caring for yourself during treatment, help set goals for living with cancer, and connect with advocacy groups and a wider community of support.

Please read full Important Safety Information on pages 8-11, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

Your out-of-pocket cost for TECVAYLI® is determined by your insurance coverage. Call a *Janssen Compass*® Care Navigator to receive personalized options to help you pay for your medication.

Here are a few of the options that may be available:

For Commercially Insured Patients: Savings Program

Eligible patients pay as little as $5 for each dose of their TECVAYLI® medication. There is a limit to savings each year. The program does not cover the cost for your healthcare provider to administer your injections. Participate without sharing your income information. See program requirements at **tecvayli.janssencarepathsavings.com**.

Call a Care Navigator to learn more about program requirements and enroll over the phone.

Other resources

A Care Navigator can be your guide to nonprofit organizations, patient advocacy groups, and state programs that may help with financial assistance.

Janssen Patient Assistance

Patient assistance from Janssen is available if you have commercial, employer-sponsored, or government coverage that does not fully meet your needs. You may be eligible to receive TECVAYLI® free of charge for up to one year. You must meet the eligibility and income requirements for the patient assistance program. See terms and conditions at **PatientAssistanceInfo.com** or contact us at 1-833-742-0791.

Visit janssencompass.com to request your first call and learn more about how *Janssen Compass*® can be here for you. You can also call us at 844-NAV-1234 (844-628-1234), Monday through Friday, 8:30 AM – 8:30 PM ET.

Visit janssencompass.com to learn about other resources available to you.

Janssen Compass® is limited to education about your Janssen therapy, its administration, and/or your disease. It is intended to supplement your understanding of your therapy and is not intended to provide medical advice, replace a treatment plan from your doctor or nurse, or serve as a reason for you to start or stay on this medication.

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with your smart phone and tap the link to **visit TECVAYLI.com** to learn more, or to sign up for additional resources

Please read full Important Safety Information on pages 8-11, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

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