


Treatment Decision Guide



Understanding how ADCETRIS plus AVD compares to ABVD chemotherapy for adults with previously untreated Stage 3 or 4 classical Hodgkin lymphoma

Amina, treated with
ADCETRIS plus AVD

What is ADCETRIS?

ADCETRIS is a medication used to treat adults with previously untreated Stage 3 or 4 classical Hodgkin lymphoma. For these patients, ADCETRIS is given in combination with AVD chemotherapy (Adriamycin, vinblastine, and dacarbazine).

Select Important Safety Information

Important Warning

PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML): Patients treated with ADCETRIS can have a rare, serious brain infection called PML that can lead to death.

Please [click here](#) to see additional Important Safety Information on page 19 and Important Facts about ADCETRIS, including BOXED WARNING, at adcetris.com.

ABVD = Adriamycin, bleomycin, vinblastine, dacarbazine.

Treatment Decision Guide

Classical Hodgkin lymphoma is a type of cancer of the blood affecting lymphocytes, a type of white blood cell.

There are many therapies for Hodgkin lymphoma. This guide explores clinical study data comparing a newer option, ADCETRIS plus chemotherapy called AVD (Adriamycin, vinblastine, and dacarbazine) for adults with previously untreated Stage 3 or 4 classical Hodgkin lymphoma, to the traditional chemotherapy-only treatment ABVD (Adriamycin, bleomycin, vinblastine, and dacarbazine).

Using This Guide

An introduction to the guide and tips on how to use this information when talking to your doctor.



What Is ADCETRIS?

How ADCETRIS works, and what makes it different from traditional chemotherapy.



Understanding Side Effects

An overview of serious ADCETRIS side effects



Study Results

Clinical trial data looking at overall survival and cancer progression, as well as updates observed at 6 years.



ADCETRIS and Peripheral Neuropathy

Information on ADCETRIS and peripheral neuropathy and how to manage common and serious side effects.



Starting Treatment

What to expect when beginning ADCETRIS treatment, including a look at dosing and administration.



ADCETRIS Resources

Links to downloadable resources for patients and caregivers considering ADCETRIS treatment.



Please [click here](#) to see additional Important Safety Information on page 19 and Important Facts about ADCETRIS, including BOXED WARNING, at adcetris.com.



How to use this guide



Each section of this Treatment Decision Guide addresses a common question many previously untreated Stage 3 or 4 classical Hodgkin lymphoma patients have about treatment with ADCETRIS plus AVD.



This Treatment Decision Guide has been designed for you. This guide aims to empower you, allowing you to take control of your health journey while considering your individual circumstances and preferences. You will find the information and tools you need to make knowledgeable treatment decisions.



Go ahead and share it with family, friends, and caregivers. You can also use it to discuss Hodgkin lymphoma treatment options with your doctor at your next appointment.



Glossary

ABVD: A combination of 4 chemotherapies—Adriamycin, bleomycin, vinblastine, and dacarbazine.

ADC: An antibody-drug conjugate, a type of targeted cancer therapy.

AVD: A combination of 3 chemotherapies—Adriamycin, vinblastine, dacarbazine.

CD30: A receptor protein on the surface of cells, present in approximately 95% of Hodgkin lymphoma cases.

FDA: The Food and Drug Administration.

G-CSF: Granulocyte colony-stimulating factor, a medication that can help boost white blood cell count.

mPFS: Modified progression-free survival, the length of time during and after treatment a patient lives without cancer progression, death, or receiving another cancer treatment.

Overall survival: The length of time that patients remain alive after starting study treatment.

Relapse: When cancer returns after a period of time when signs and symptoms of disease lessen or disappear.

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Advocating for yourself



Amina, treated with ADCETRIS plus AVD

Your first treatment choice matters

Your voice matters when it comes to making a treatment decision for previously untreated Stage 3 or 4 classical Hodgkin lymphoma.

If your doctor doesn't mention ADCETRIS as an option, it's OK to ask about it. Don't hesitate to speak up and ask questions. Familiarize yourself with all available treatments and seek a second opinion if that will help you feel confident about your treatment choice. While your doctor is the expert regarding your diagnosis, **you and your care team are equal partners in the treatment decision.** Your perspective and concerns play an essential role in selecting a treatment that works for you.

Use this guide to review these 2 treatments and weigh their benefits and risks so you can feel comfortable discussing ADCETRIS plus AVD with your doctor.



of people with previously untreated Stage 3 or 4 Hodgkin lymphoma relapsed or didn't respond after treatment with ABVD (traditional chemotherapy).

Reported in 2 medical journals: *Lancet* and *New England Journal of Medicine*.



“To me, self-advocacy means being brave enough to ask questions.”

Amina, patient treated with ADCETRIS plus AVD



“Do your own research. Learn about all your treatment options. My first doctor never even told me ADCETRIS plus AVD was an option I could consider.”

Brandon, patient treated with ADCETRIS plus AVD

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Could a more targeted alternative to ABVD be right for your Stage 3 or 4 classical Hodgkin lymphoma diagnosis?

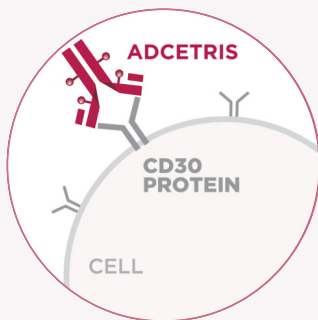


What Is ADCETRIS?

ADCETRIS is not chemotherapy, but is given together with the chemotherapy regimen AVD. ADCETRIS is an antibody-drug conjugate (ADC), a drug made up of 3 parts that works by targeting CD30, a protein on the surface of certain cells, including Hodgkin lymphoma cells.

ADCETRIS plus AVD

HOW IT WORKS:



ADCETRIS is an **ADC** that aims to **target a protein called CD30**, found on the surface of Hodgkin lymphoma cells.* Oncologists call this ability to target Hodgkin's cells "CD30 directed."

ADCETRIS takes the place of bleomycin in the ABVD chemotherapy treatment regimen.

*Even though CD30 is not commonly found on healthy cells, ADCETRIS may still harm normal cells and cause side effects. Talk to your doctor if you have questions about side effects.

ABVD

Chemotherapy uses **cytotoxic agents**, or drugs with the ability to kill fast-growing cells. These drugs may attack any cells in the body that are dividing, including cancer cells and healthy cells.

The ABVD regimen is also prescribed for classical Hodgkin lymphoma as a first treatment option, and includes the drugs Adriamycin, bleomycin, vinblastine, and dacarbazine.

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Over 12 years of dedication to patients



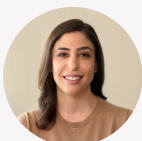
Mary Ann, treated with ADCETRIS plus AVD

While the science behind ADCs is more novel than traditional chemotherapy, ADCETRIS is a well-established treatment for certain types of lymphoma since 2011.

- Nearly 1700 patients with certain types of lymphoma received treatment with ADCETRIS across 8 clinical trials
- Over 62,000 patients in the US and over 156,000 patients worldwide have been treated with ADCETRIS since 2011
- ADCETRIS continues to be studied by researchers today

ADCETRIS is FDA-approved across 8 indications

<ul style="list-style-type: none"> • Adults with classical Hodgkin lymphoma after a stem cell transplant fails or after at least 2 chemotherapy treatments fail and stem cell transplant is not an option • Adults with systemic anaplastic large cell lymphoma after at least 1 combination chemotherapy treatment fails 	<p>Adults with primary cutaneous anaplastic large cell lymphoma or CD30-expressing mycosis fungoides after systemic therapy (drugs that spread throughout the body)</p>	<p>Children 2 years of age and older with previously untreated high risk classical Hodgkin lymphoma, in combination with chemotherapy (doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide)</p>
<p>2011</p> <p>Adults with classical Hodgkin lymphoma at high risk of coming back or becoming worse after a stem cell transplant</p>	<p>2017</p>	<p>2022</p>
<ul style="list-style-type: none"> • Adults with previously untreated Stage 3 or 4 classical Hodgkin lymphoma, in combination with chemotherapy (Adriamycin, vinblastine, and dacarbazine) • Adults with previously untreated systemic anaplastic large cell lymphoma or other CD30-expressing peripheral T-cell lymphomas, including angioimmunoblastic T-cell lymphoma and peripheral T-cell lymphomas not otherwise specified, in combination with chemotherapy (cyclophosphamide, doxorubicin, and prednisone) 	<p>2018</p>	<p>2025</p> <p>Adults with relapsed or refractory Large B-Cell Lymphoma (LBCL), including diffuse large b-cell lymphoma (DLBCL) not otherwise specified (NOS), DLBCL rising from indolent lymphoma, or high-grade B cell lymphoma (HGBCL), after two or more lines of systemic therapy who are not eligible for HSCT or CAR-T cell therapy, in combination with lenalidomide and a rituximab product.</p>



“I liked that ADCETRIS plus AVD was FDA approved for previously untreated Stage 3 or 4 classical Hodgkin lymphoma and had many years of data. This made me feel confident in my choice.”

Mary Ann, patient treated with ADCETRIS plus AVD

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Do you have questions about ADCETRIS plus AVD side effects?

PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML):

Patients treated with ADCETRIS can have a rare, serious brain infection called PML that can lead to death. Tell your doctor immediately if you have mood or behavior changes, confusion, problems in thinking or loss of memory, changes in vision, speech, or walking, or decreased strength or weakness on one side of the body. PML may also be caused by prior treatments or diseases that weakened your immune system.

Do not take ADCETRIS with bleomycin because of possible serious side effects to the lungs. These are not the only side effects of ADCETRIS. Always tell your doctor about any side effects you experience.



Other possible serious side effects in the clinical study

ADCETRIS can cause other **serious side effects**, including:

- **Nerve damage** (peripheral neuropathy)
- **Allergic and infusion reactions.** Allergic reactions, including severe forms, during infusion or up to 24 hours after ADCETRIS infusion. If you have a reaction to the infusion, you may be given medicines before your ADCETRIS treatment
- **Blood problems/fever.** Serious cases, including death, of fever with a low number of white blood cells (neutropenia) or weakened immune system have occurred with ADCETRIS
- **Infections.** Serious infections and infections caused by bacteria, fungi, or viruses have been reported after treatment with ADCETRIS
- **Tumor lysis syndrome (TLS).** TLS is caused by the fast breakdown of cancer cells. Your doctor may do blood tests to check you for TLS
- ADCETRIS patients with **severe kidney problems or moderate or severe liver problems** may have more side effects and deaths than patients without kidney or liver problems. Tell your doctor if you have or have had any kidney or liver problems
- **Liver problems.** Serious liver problems, including death, have been reported after treatment with ADCETRIS
- **Lung problems.** Serious lung problems, including death, have been reported after treatment with ADCETRIS
- **Skin problems.** Rare but serious skin conditions, including death, have been reported after treatment with ADCETRIS
- **Gastrointestinal (GI) problems.** Serious problems, including death, related to the pancreas, stomach, intestine, and colon have been reported

- **High blood sugar (hyperglycemia).** You can develop high blood sugar after treatment with ADCETRIS

The **most common side effects (≥20%) in adult patients** who received ADCETRIS are:

- nerve damage (peripheral neuropathy)
- nausea
- feeling tired
- muscle pain
- constipation
- diarrhea
- vomiting
- fever
- infection in the nose or sinuses
- sores or swelling in the mouth and/or in the digestive tract
- upper stomach pain
- rash

The **most common laboratory abnormalities (≥20%) in adult patients** who received ADCETRIS are:

- a decrease in white blood cells
- an increase in creatinine
- a decrease in hemoglobin
- an increase in blood sugars
- an increase in alanine aminotransferase (ALT)
- an increase of aspartate aminotransferase (AST)

The **most common severe side effects (≥5%) in pediatric patients** who received ADCETRIS are:

- a low number of white blood cells
- a low number of red blood cells
- a low number of platelets
- fever with a low number of white blood cells
- sores or swelling in the mouth
- infection

Call your doctor right away if you have any of the signs or symptoms of the serious side effects listed above.

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Understanding study endpoints

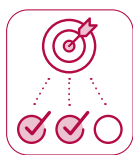


Study endpoints

Study endpoints are measures defined before a trial starts to find out if a treatment may be safe or effective. They help answer questions, such as, is the treatment shrinking the tumor? Or, is the person living longer?

Medicines have to show that the benefit they provide to the patient may outweigh whatever risk they pose. For cancer treatments, those benefits are generally increased survival and/or an improvement in symptoms. Common study endpoints in cancer trials are overall survival, or the length of time that patients remain alive after starting the study treatment, and progression-free survival, or the amount of time after the start of treatment a patient is alive and their cancer doesn't grow or spread.

During some clinical trials, additional exploratory observations are made outside of what the trial was designed to study specifically. Exploratory observations can include a simple count of how many times a certain event happened, but they are not predesigned to explain why something happened and cannot be used to state that something is more likely to occur with one treatment versus another. They also cannot be used to state how likely it would be to see similar results outside of the clinical study, but they may provide helpful information to be discussed with your care team.



How do endpoints and goals affect treatment decisions?

When deciding on a treatment, your oncologist may look at many clinical studies and assess different study endpoints, including overall survival and progression-free survival. These endpoints can be helpful in choosing the right treatment for you and figuring out how likely you are to meet your goals.

When it's time to choose a treatment, ask questions and voice your concerns. That way, you can feel confident in choosing the right treatment option for your needs.

On the following pages, you'll find information about the ECHELON-1 study and how well ADCETRIS worked in previously untreated patients with Stage 3 or 4 classical Hodgkin lymphoma



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brentuximab vedotin | injection 50 mg

ECHELON-1 study design information

ECHELON-1 was a large, international, clinical study of 1334 people that compared 2 therapies in patients with previously untreated Stage 3 and 4 classical Hodgkin lymphoma:

- ADCETRIS given together with AVD chemotherapy (Adriamycin, vinblastine, and dacarbazine)
 - 664 people received ADCETRIS plus AVD every 2 weeks for up to 12 doses
- ABVD, a conventional chemotherapy regimen of Adriamycin, bleomycin, vinblastine, and dacarbazine
 - 670 people received ABVD every 2 weeks for up to 6 cycles of 28 days each

Researchers looked at the effectiveness and safety of these treatments at approximately 2 years and collected data about long-term results at 6 years.

APPROXIMATELY 6 YEARS AFTER TREATMENT

Overall survival was significantly higher with ADCETRIS plus AVD compared to ABVD chemotherapy

- The following data represent the overall survival that was observed after 6 years
- Overall survival is the length of time, from the start of treatment, that patients are still alive
- These data are the secondary endpoint in the study
- The median follow-up time was 6.1 years
- Median overall survival was not reached in either treatment group



41% REDUCED RISK OF DEATH
FOR PATIENTS TREATED WITH ADCETRIS PLUS AVD
COMPARED TO TRADITIONAL ABVD CHEMOTHERAPY

- About **94% of adults treated with ADCETRIS plus AVD**, and about 89% of adults treated with ABVD, **were still alive at approximately 6 years**

Median: The middle number in a list of numbers.

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AFTER 2 YEARS OF FOLLOW UP

ADCETRIS plus AVD was more effective than ABVD

- The following data represent the modified progression-free survival that was observed at 2 years
- Modified progression-free survival means the length of time during and after treatment a patient lives without cancer progression, death, or receiving another cancer treatment
- These data are the primary endpoint in the study, and these results were used to help support the FDA approval of ADCETRIS plus AVD
- The median follow-up time was just over 2 years (24.6 months)

**23%****REDUCED RISK**

OF CANCER GROWING OR SPREADING, OR RECEIVING ADDITIONAL ANTICANCER THERAPY, OR DEATH WITH ADCETRIS PLUS AVD compared to traditional ABVD chemotherapy

- About **82%** of adults treated with ADCETRIS plus AVD **did not have their cancer grow or spread, need additional anticancer therapy, or die** compared to about 77% of adults treated with traditional ABVD chemotherapy

Median: The middle number in a list of numbers.

ADCETRIS will not work for everyone. Individual results may vary.

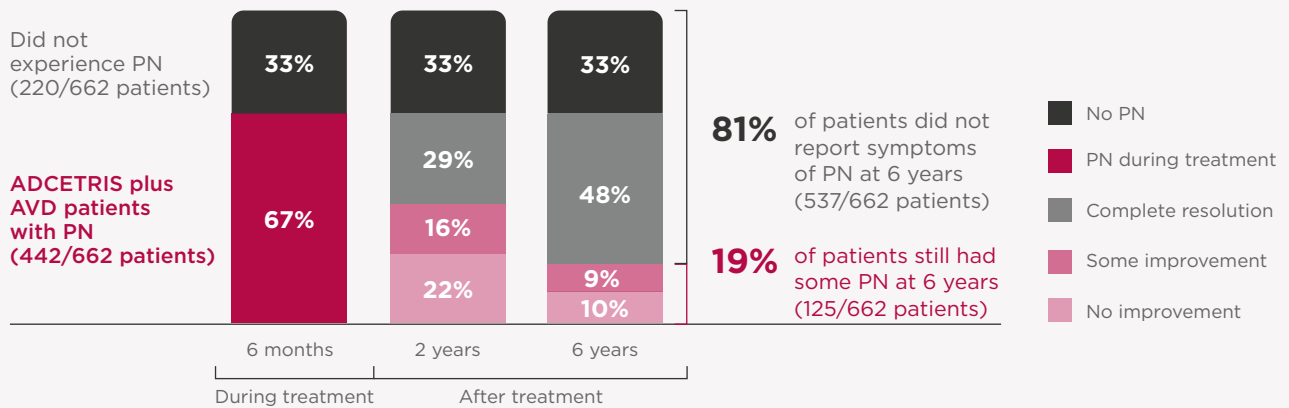
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Most ADCETRIS plus AVD patients who experienced peripheral neuropathy during the study saw it lessen or go away completely over time

Peripheral neuropathy (PN; also called neuropathy) is nerve damage that causes symptoms such as tingling in the hands or feet (known as sensory PN), or weakness in the arms or legs (motor PN). Most PN observed in the study was sensory and considered cumulative. While some patients developed severe PN, most was mild or moderate.

Peripheral neuropathy reported in the ADCETRIS clinical trial



Tell your doctor about any side effect concerns you have

Your doctor should prescribe granulocyte colony-stimulating factor (G-CSF) along with your ADCETRIS treatment right at the start. G-CSF is a medication that may help reduce the chance of neutropenia (low white blood cell count).

Don't stop, change, or delay your ADCETRIS plus AVD treatment unless directed by your doctor. Your doctor may take additional steps to help manage side effects, including:

- Reducing your ADCETRIS dosage, or delaying your next dose, until symptoms improve
- Stopping ADCETRIS completely if side effects are severe or do not improve



Do you have more questions about side effects?

Note them here and use them as conversation starters with your doctor.

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Model portrayal

Ask your doctor what long-term data are available and what they could mean

Have you asked your doctor to discuss the possibility of secondary cancer?

People who have had cancer before are at an increased risk of developing another type of cancer. Sometimes, it is more than 10 years after treatment of their first cancer, but it can be sooner. According to the American Cancer Society, people who have had Hodgkin lymphoma have an increased risk of certain cancers. These secondary cancers may be linked to the therapies used to help treat Hodgkin lymphoma. Secondary cancers are one of the long-term considerations to discuss with your doctor.

Exploratory observation: ECHELON-1 secondary cancer observed at 6 years

Roughly 6 years after patients started their treatment in the ECHELON-1 study, the study investigators observed the number of patients who had developed a secondary cancer. ECHELON-1 was not designed to show a difference between the 2 treatment groups; therefore, the observation cannot be used to determine if the number of secondary cancers differed depending upon the treatment study participants received. No conclusions can be made about this data, including which treatment is better or worse.

Secondary cancers observed in ECHELON-1

Total	55 out of 1321 people
ADCETRIS plus AVD	23 out of 662 people
ABVD	32 out of 659 people

There is risk regardless of treatment, as 55 people out of 1321 (4.2%) developed a secondary cancer.

More study information was published in the *New England Journal of Medicine* on July 13, 2022. The publication is called "Overall Survival with Brentuximab Vedotin in Stage III or IV Hodgkin's Lymphoma" by SM Ansell, et al.



This information is meant to help you engage in discussions with your doctor. You should always consult with your doctor to discuss and understand clinical data.

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You should talk to your doctor about pregnancy and family planning

If you or a partner undergoing Hodgkin's treatment wish to start a family, ask your doctor about the risks associated with treatment and the options that may be available.

You should know that if you are pregnant or plan to become pregnant, ADCETRIS treatment may harm your unborn baby. Also, if you are breastfeeding or plan to breastfeed, ADCETRIS treatment may harm your nursing baby.

- **Females who are able to become pregnant:** Your doctor should give you a pregnancy test before starting ADCETRIS treatment. You should use effective birth control during ADCETRIS treatment and for 2 months after your last dose of ADCETRIS. Tell your doctor right away if you become pregnant or think you are pregnant during ADCETRIS treatment
- **Men with female partners who can get pregnant:** You should use effective birth control during ADCETRIS treatment and for 4 months after the last dose
- **Females who are breastfeeding or plan to breastfeed:** Do not breastfeed during treatment with ADCETRIS. Tell your doctor if you are breastfeeding or plan to breastfeed

Exploratory observation: Births reported 6 years after treatment in ECHELON-1

Roughly 6 years after patients started their treatment in the ECHELON-1 study, the study investigators observed the number of female patients and female partners of male patients who had a "live birth" (a child born alive). Female patients who were breastfeeding or who had a positive pregnancy test before the study began were excluded from the clinical trial because of possible risks associated with treatment. Female patients were also advised of the risks of pregnancy and breastfeeding with ADCETRIS treatment.

These observations are considered exploratory because ECHELON-1 was not designed to find the differences or benefits between the 2 treatment groups on the likelihood of live births following treatment. They also can't be used to determine if the number of live births differed because of the treatment that the study participants received. No conclusions can be made about this data, including which treatment is better or worse.

TOTAL CHILDREN
BORN ALIVE IN
BOTH GROUPS

155*

Neither ECHELON-1 nor the exploratory observations evaluated fertility, and they couldn't prove the likelihood of a live birth with either treatment.

It is not known how many of the 1321 study participants intended to or tried to have children. This means that we do not know the total number of possible births. 155 represents the number of children born alive who were reported by study participants at the 6-year follow up.

More study information was published in the *New England Journal of Medicine* on July 13, 2022. The publication is called "Overall Survival with Brentuximab Vedotin in Stage III or IV Hodgkin's Lymphoma" by SM Ansell, et al.



If family planning is important to you, consult your doctor to understand any risks and options that may be available to you.

*96 children were born alive in the ADCETRIS plus AVD group, and 59 children were born alive in the ABVD group. Because some female patients and female partners of male patients had more than one live birth, the 155 children do not represent how many unique individuals reported a live birth. All live births may not have been reported.

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Did you know ADCETRIS plus AVD is given in a similar way to traditional ABVD chemotherapy?

What to expect when starting treatment

ADCETRIS plus AVD	ABVD
<p>HOW is treatment given?</p>	<p>By intravenous (IV) infusion, directly into a vein.</p>
<p>WHERE will I receive treatment?</p>	<p>At your doctor's office or infusion center.</p>
<p>WHAT is a typical dose?</p>	<p>Dosage is calculated based on body weight.</p>
<p>HOW LONG will treatment last?</p>	<p>Up to 6 months, depending on your body's response to treatment and if you have serious side effects.</p>



The recommended dosage of ADCETRIS in combination with AVD chemotherapy is 1.2 mg/kg of body weight, to a maximum of 120 mg. You will receive ADCETRIS every 2 weeks, up to a maximum of 12 doses. Your doctor may modify this dosage or discontinue treatment if you have kidney or liver problems or experience certain side effects.



The ADCETRIS infusion takes approximately 30 minutes, and additional time is required to receive AVD. You may need to arrive at your appointments early to prepare and/or stay afterward for routine monitoring.

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Brandon, treated with ADCETRIS plus AVD

From cost to resources, support may be available

The patient support programs available through Pfizer are designed to help patients begin their prescribed ADCETRIS treatment. If eligible and enrolled, you can receive personalized support, including:

- Confirming your insurance coverage
- Evaluating out-of-pocket costs and available copay options
- Helping you access alternative support options if you can't afford ADCETRIS*

Talk to your healthcare provider to learn how to enroll in the Pfizer Patient Assistance Program.

Visit the website >

Information provided by patient support programs from Pfizer is not intended to be a substitute for your healthcare provider. Discuss any questions you may have about your disease and your treatment with your healthcare team.

*Financial support may be provided through foundation referral. Pfizer does not guarantee that enrollment will result in coverage and/or reimbursement.



Do you have more questions about starting treatment?

Note them here and use them as conversation starters with your doctor.

*Terms and conditions may apply for patient support programs provided by Pfizer. Please work directly with your healthcare provider to contact Pfizer for more details.

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Justin, treated with
ADCETRIS plus AVD

Treatment resources

If you have recently received a Stage 3 or 4 classical Hodgkin lymphoma diagnosis or are caring for someone who has, these resources provide more information about ADCETRIS treatment and support.



Doctor Discussion Guide

Questions you can use at your next appointment to help start the conversation about ADCETRIS treatment.



Resources on ADCETRIS.com

Information regarding ADCETRIS costs and coverage, mobile apps to help manage treatment, inspiring stories from ADCETRIS patients, and connections to organizations devoted to lymphoma research and care.



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Important Safety Information

What is the most important serious safety information I should know about ADCETRIS?

- **PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML): Patients treated with ADCETRIS can have a rare, serious brain infection called PML that can lead to death.** Tell your doctor immediately if you have mood or behavior changes, confusion, problems in thinking or loss of memory, changes in vision, speech, or walking, or decreased strength or weakness on one side of the body. PML may also be caused by prior treatments or diseases that weakened your immune system.
- **Do not take ADCETRIS** if you are receiving bleomycin

What are the other possible serious side effects of ADCETRIS?

- **Nerve damage (peripheral neuropathy).** Tell your doctor if you have any numbness or tingling in your hands or feet or any muscle weakness.
- **Allergic and infusion reactions.** Tell your doctor if you experience symptoms of fever, chills, rash, or breathing problems within 24 hours of infusion. If you have a reaction, you may be given medicines before your ADCETRIS treatment.

• **Blood problems.** Serious cases, including death, of fever with a low number of white blood cells have occurred with ADCETRIS. Serious cases of a low number of white blood cells, a low number of platelets, or a low number of red blood cells can occur.

Your doctor will do blood tests to check your blood cell levels during ADCETRIS treatment. Your doctor may give you a medicine called G-CSF. Tell your doctor if you have a fever of 100.5°F or higher, chills, cough, or pain when you urinate.

- **Infections** caused by bacteria, fungi, or viruses have been reported.
- **Tumor lysis syndrome** is caused by the fast breakdown of cancer cells. Your doctor will monitor you for symptoms.
- **Patients with severe kidney disease or moderate or severe liver disease** may have more side effects and deaths than patients without kidney or liver problems.
- **Liver problems.** Serious liver problems, including death, can occur. Tell your doctor if you feel tired, do not feel like eating, have upper stomach pain, dark urine, or yellow skin and eyes (jaundice).
- **Lung problems.** Serious lung problems, including death, can occur. Tell your doctor if you have a new cough, a cough that gets worse, or feel out of breath.
- **Skin problems** called Stevens-Johnson syndrome and toxic epidermal necrolysis can happen. Tell your doctor if you have rash, hives, sores in your mouth, or blistering or peeling skin.
- **Gastrointestinal (GI) problems.** Serious cases, including death, related to the pancreas, stomach, intestine, and colon can happen. If you have lymphoma that involves your stomach or intestine, you could have a higher risk of GI problems. Tell your doctor if you have severe stomach pain, chills, fever, nausea, vomiting, or diarrhea.
- **High blood sugar.** Your doctor will test your blood during ADCETRIS treatment. Tell your doctor if you need to urinate more often than usual, are very thirsty, or have blurry vision.

The most common side effects (≥20%) in adult patients who received ADCETRIS are:

- nerve damage (peripheral neuropathy)
- nausea
- feeling tired
- muscle pain
- constipation
- diarrhea
- vomiting
- fever
- infection in the nose or sinuses
- sores or swelling in the mouth and/or in the digestive tract
- upper stomach pain
- rash

The most common laboratory abnormalities (≥20%) in adult patients who received ADCETRIS are:

- a decrease in white blood cells
- an increase in creatinine
- a decrease in hemoglobin
- an increase in blood sugars
- an increase in alanine aminotransferase (ALT)
- an increase of aspartate aminotransferase (AST)

The most common severe side effects (≥5%) in pediatric patients who received ADCETRIS are:

- a low number of white blood cells
- a low number of red blood cells
- a low number of platelets
- fever with a low number of white blood cells
- sores or swelling in the mouth
- infection

These are not all the possible side effects of ADCETRIS. Tell your doctor about any side effect that bothers you or does not go away. If you have certain side effects, your doctor may lower your dose, delay, or stop your ADCETRIS treatment.

What should I tell my doctor before I start treatment with ADCETRIS?

- **All your medical conditions**, including if you have kidney, liver, or lung problems, an infection, or diabetes.
- **If you are pregnant or plan to become pregnant.** ADCETRIS may harm your unborn baby. **Females who are able to become pregnant:** Your doctor should give you a pregnancy test before starting ADCETRIS treatment. You should use effective birth control during ADCETRIS treatment and for 2 months after your last dose of ADCETRIS. Tell your doctor right away if you become pregnant or think you are pregnant during ADCETRIS treatment. **Men with female partners who can get pregnant** should use effective birth control during ADCETRIS treatment and for 4 months after the last dose.
- **If you are breastfeeding or plan to breastfeed.** Do not breastfeed during ADCETRIS treatment.
- **All the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ADCETRIS and certain other medicines can affect each other.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/Safety/MedWatch or call 1-800-FDA-1088.

Please see Important Facts about ADCETRIS, including BOXED WARNING, at adcetris.com.

