

PICTURE YOUR

ONE DOSE LIFE

A step-by-step guide to treatment with ITVISMA

Lab tests and administration of oral corticosteroids are required before and after injection.

Scarlette R., 17 years old
Student
Living with spinal muscular atrophy (SMA)

Scarlette hasn't received ITVISMA. Individuals shown were compensated for their time.

Once you and your doctor have chosen ITVISMA, there are important details that need to be taken care of. This guide goes over key steps to help the process go smoothly.

What is ITVISMA?

ITVISMA is a prescription gene therapy used to treat adults and children 2 years of age and older with spinal muscular atrophy (SMA). ITVISMA is given as a one-time intrathecal injection.

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

- ITVISMA can increase liver enzyme levels and cause hepatotoxicity.
- Patients will receive an oral corticosteroid medication before and after ITVISMA injection and will undergo regular blood tests to monitor liver function.
- Patients and caregivers should contact the patient's doctor immediately if the patient's skin and/or whites of the eyes become yellowish, if the patient misses a dose of corticosteroid or vomits it up, or if the patient experiences a decrease in alertness.

Please see additional Important Safety Information on [page 8](#) and [Full Prescribing Information](#).

 **itvisma**[®]
(onasemnogene abeparvovec-brve)
suspension for intrathecal injection



RECEIVING ITVISMA

IMPORTANT LAB TESTS AND FORMS

Scarlette lives with SMA and hasn't received ITVISMA. Individuals shown were compensated for their time.

The doctor will schedule lab tests to help determine if ITVISMA is right for you or your loved one.

It's generally best to have the tests completed promptly to ensure a smooth start to treatment.

Anti-AAV9 antibody test
 ITVISMA is delivered using a modified virus called adeno-associated virus serotype 9 (AAV9).
 Before treatment, a blood test is needed to measure anti-AAV9 antibody levels.

Date: _____
 Time: _____
 Location: _____

Baseline blood tests
 Before starting treatment with ITVISMA, the doctor will order blood tests. These tests ensure eligibility to receive ITVISMA and are later used to monitor health after treatment. They typically include checks for liver function, creatinine levels, and complete blood count.

Date: _____
 Time: _____
 Location: _____

The results of these tests may be available in a few days, though sometimes it takes a bit longer. Ask the doctor if you have any questions about these tests, including what these tests are, why they are needed, and when you may expect to receive results.

Talk to your doctor about your vaccination status, including the seasonal influenza and respiratory syncytial virus (RSV) vaccines.

Please see the Indication and Important Safety Information on [page 8](#) and [Full Prescribing Information](#).



RECEIVING ITVISMA

IMPORTANT LAB TESTS AND FORMS

While waiting for the lab test results, ask the doctor to submit the Novartis Patient Support™ Start Form

Once the completed and signed Novartis Patient Support Start Form is submitted, you or your loved one will be enrolled with Novartis Patient Support and connected with a Novartis Patient Support Case Coordinator who will be your main, dedicated point of contact. Case Coordinators can provide insurance support, financial support, and ongoing support for eligible people prescribed ITVISMA.

Dedicated assistance from Novartis Patient Support and educational resources help people get started on treatment and support them along the way. Novartis Patient Support is not a clinical service and does not replace guidance from health care providers. Their goal is to help people feel informed about their treatment from day one.

[Learn more about Novartis Patient Support and how the support team can help you.](#)

Case Coordinator:

Name: _____

Email: _____

Phone number: _____

Please see the Indication and Important Safety Information on [page 8](#) and [Full Prescribing Information](#).



Andrew C., 22 years old
Sports journalist and student
Living with spinal muscular atrophy (SMA)

Andrew hasn't received ITVISMA and was compensated for his time.

GETTING ITVISMA

WORKING WITH YOUR INSURANCE

Scarlette lives with SMA and hasn't received ITVISMA. She was compensated for her time.

Your next step is to get insurance approval. The doctor's office will complete and submit prior authorizations and fulfill any appeal requirements.

Be sure to:

- Work with the doctor to help ensure all lab tests are completed
- Notify the doctor if additional information is needed
- Give Novartis Patient Support™ your coverage information
- Ask Novartis Patient Support if financial assistance programs are available to you

Have questions?
Reach out to your Novartis Patient Support Case Coordinator at **1-855-441-4363**. They're here to help!

[Learn more about insurance coverage for ITVISMA.](#)

If you or your loved one is enrolled in Novartis Patient Support, your dedicated Case Coordinator is here when you need them.

Case Coordinators can provide insurance support, financial support, and ongoing support for eligible patients prescribed ITVISMA, including:

- Explaining the steps before and after treatment with ITVISMA
- Helping navigate the insurance and reimbursement process, including benefits verification and support with prior authorization and appeals
- Identifying financial support options and eligibility
- Tracking treatment with ITVISMA from prescription to delivery at the site of administration

Please see the Indication and Important Safety Information on [page 8](#) and [Full Prescribing Information](#).

 **itvisma**[®]
(onasemnogene abeparvovec-brve)
suspension for intrathecal injection

HOW TO

PREPARE FOR TREATMENT



Here are things you can do in advance to help treatment day go smoothly.

Confirm the treatment date, time, and location with the doctor or care team before treatment administration. Additionally, ask about the treatment center's policy regarding who or what can be brought on treatment day

Date: _____ **Time:** _____ **Location:** _____

Check if any additional tests are needed before treatment, and review lab results to make sure everything is ready. It's best to complete any required tests as soon as possible. If the doctor orders more lab tests, you may want to write down the test name and the appointment details here:

Additional tests: _____

Watch for signs of infection and **notify the doctor right away** if you or your loved one begins coughing, wheezing, or sneezing, has a runny nose or sore throat, or develops a fever

Limit contact with others to reduce the risk of illness. Practice good hand hygiene like coughing or sneezing into a tissue and washing your hands with soap and water for at least 20 seconds

Ask the doctor if you have any specific, unanswered questions, such as information about:

- The treatment administration
- Posttreatment follow-up and monitoring
- The schedule for treatment day
- Whether additional baseline blood tests are needed

Pack a bag with everything you or your loved one may need to be comfortable on treatment day (treatment centers may not have the refreshments and equipment you'll need)

Fill the prescription for the oral corticosteroid as soon as you or your loved one gets it (your pharmacy may have to order it)

Take or have your loved one take the prescribed oral corticosteroid the day before ITVISMA injection, as directed by your or your loved one's doctor. The doctor will discuss this in more detail, including the time of day to take the medication and what directions to follow

Please see the Indication and Important Safety Information on [page 8](#) and [Full Prescribing Information](#).

 **itvisma**[®]
(onasemnogene abeparvovec-brve)
suspension for intrathecal injection

WHAT TO EXPECT ON

TREATMENT DAY



Now that you have the prep work behind you, you or your loved one is all set for treatment day. And as always, your Case Coordinator is there to support you and your family.

Things to know before arriving for treatment:

Confirm the logistics for the big day, including: arrival time, where in the hospital the treatment will take place, and who to ask for when you arrive

Arrival time: _____ Location in hospital: _____
Contact name: _____ Contact phone: _____

Expect the injection itself to take about 1 to 2 minutes. However, treatment will take longer and sedation or imaging may be needed. You or your loved one will be asked to remain at the treatment center for a period of time after the treatment; ask the doctor in advance how long you'll be required to stay

Wait time after injection: _____

Before you and/or your loved one leave the treatment center:

Talk to the doctor about what to expect after treatment

Confirm follow-up appointments for testing and monitoring

When you get home:

Continue to take the corticosteroid as prescribed, and notify the doctor if a dose is missed or not tolerated

Contact the doctor immediately if you notice:

- Any signs of infection, including coughing, wheezing, sneezing, runny nose, sore throat, or fever
- Yellowish appearance of the skin or whites of the eyes
- A decrease in alertness
- Sensory disturbances such as numbness, tingling, or pain in arms, hands, legs, and/or feet
- Unexpected bruising or bleeding
- Seizures
- Decreased urine output
- Any other symptoms the doctor may tell you about

Please see the Indication and Important Safety Information on [page 8](#) and [Full Prescribing Information](#).

 **itvisma**[®]
(onasemnogene abeparvovec-brve)
suspension for intrathecal injection



AFTER TREATMENT

ONGOING SMA CARE

Andrew lives with SMA and hasn't received ITVISMA. Individuals shown were compensated for their time.

Here are some key points for care moving forward:

Complete blood test appointments for at least 3 months after treatment, as directed by the doctor

Continue the oral corticosteroid as prescribed by the doctor

Speak with a neuromuscular specialist to determine the best care possible. Your or your loved one's health care team may recommend:

- Physical and occupational therapy
- Working with a nutritionist
- Consulting with a:
 - Pulmonologist (who specializes in the lungs)
 - Gastroenterologist (who specializes in the digestive system)
 - Orthopedist (who specializes in bone health)

Ask about additional support (as needed), such as:

- Physical bracing and other supportive equipment
- Additional wellness visits

Maintain routine checkups and vaccinations, and review any additional spinal muscular atrophy (SMA) support and goals you have

Care for yourself. There are many demands on friends and families, and it can affect everything from your health to your relationships

Notes:

Please see the Indication and Important Safety Information on [page 8](#) and [Full Prescribing Information](#).

 **itvisma**[®]
(onasemnogene abeparvovec-brve)
suspension for intrathecal injection

INDICATION AND IMPORTANT SAFETY INFORMATION

What is ITVISMA?

ITVISMA is a prescription gene therapy used to treat adults and children 2 years of age and older with spinal muscular atrophy (SMA). ITVISMA is given as a one-time intrathecal injection.

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

- ITVISMA can increase liver enzyme levels and cause hepatotoxicity.
- Patients will receive an oral corticosteroid medication before and after ITVISMA injection and will undergo regular blood tests to monitor liver function.
- Patients and caregivers should contact the patient's doctor immediately if the patient's skin and/or whites of the eyes become yellowish, if the patient misses a dose of corticosteroid or vomits it up, or if the patient experiences a decrease in alertness.

What should I watch for before and after injection with ITVISMA?

- Infections before or after ITVISMA injection can lead to more serious complications. Patients, caregivers, and close contacts of the patient should follow infection prevention procedures. Patients and caregivers should contact the patient's doctor immediately if the patient experiences any signs of a possible infection such as coughing, wheezing, sneezing, runny nose, sore throat, or fever.
- Decreased platelet counts could occur following injection with ITVISMA. Seek immediate medical attention if the patient experiences unexpected bleeding or bruising.
- Peripheral sensory neuropathy has occurred with ITVISMA administration. Patients and caregivers should contact the patient's doctor right away if the patient experiences numbness, tingling, prickling, or pain in the arms, hands, legs, and/or feet.
- Decreased blood platelet and red blood cell counts, sudden kidney change, and increased bruising or bleeding, which could be signs of thrombotic microangiopathy (TMA), can occur. Patients and caregivers should seek immediate medical attention if the patient experiences unexpected bruising or bleeding, seizures, or decreased urine output.

- There is a theoretical risk of tumor development with gene therapies such as ITVISMA. Patients and caregivers should contact the patient's doctor and Novartis Gene Therapies, Inc. at 1-833-828-3947 if a tumor develops.

What do I need to know about vaccinations and ITVISMA?

- Patients and caregivers should consult the patient's doctor about vaccinations and ITVISMA.
- Patients and caregivers should talk with the patient's doctor to determine if adjustments to the patient's vaccination schedule are necessary during corticosteroid use.
- Protection against influenza and respiratory syncytial virus (RSV) is recommended, and vaccination status should be up-to-date prior to ITVISMA administration.

What do I need to know about contraception and egg or sperm donation and ITVISMA?

- Women of childbearing potential should use an effective method of contraception and refrain from egg donation for 6 months following ITVISMA injection.
- Men capable of fathering a child should use a barrier method of contraception and refrain from sperm donation for 3 months following ITVISMA injection.

What are the possible or likely side effects of ITVISMA?

- The most common adverse reactions that occurred in patients treated with ITVISMA were upper respiratory tract infection, fever, upper gastrointestinal symptoms, increased liver enzymes, headache, dizziness, pain in extremity, low platelet counts, and sensory disturbance.

The safety information provided here is not comprehensive. Talk to the patient's doctor about any side effects that bother the patient or that don't go away.

You are encouraged to report suspected side effects by contacting the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch, or Novartis Gene Therapies, Inc. at 1-833-828-3947.

Please see the [Full Prescribing Information](#).



Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

© 2025 Novartis

11/25

FA-11496199

 **itvisma**[®]
(onasemnogene abeparvec-brve)
suspension for intrathecal injection

Important lab tests and forms

Working with your insurance

Prepare for treatment

Treatment day

Ongoing SMA care

Important Safety Information

prev