CELEBRATE THIS MOMENT

The FDA-approved gene therapy for Duchenne

Austin
Received treatment with ELEVIDYS

IMPORTANT SAFETY INFORMATION

What is ELEVIDYS?

ELEVIDYS is a prescription gene therapy used to treat ambulatory individuals at least 4 years old with Duchenne muscular dystrophy (DMD) who have a confirmed mutation in the *DMD* gene.

ELEVIDYS is approved under accelerated approval for non-ambulatory patients at least 4 years old with DMD who have a confirmed mutation in the *DMD* gene. Accelerated approval allows for drugs to be approved based on a marker that is considered reasonably likely to predict a clinical benefit. ELEVIDYS treatment increased the marker, ELEVIDYS micro-dystrophin in skeletal muscle. Verification of a clinical benefit may be needed for ELEVIDYS to continue to be approved for non-ambulatory patients with DMD.

Who should not receive ELEVIDYS?

Individuals with certain types of mutations, any deletion in exon 8 and/or exon 9 in the *DMD* gene, should not receive ELEVIDYS.

Please see additional Important Safety Information and full Prescribing Information.

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suspension for intravenous infusion

Jaylen
Received treatment
with ELEVIDYS

The only FDA-approved gene therapy for Duchenne

- Demonstrated **increase in ELEVIDYS micro-dystrophin** in muscles
- Positive **impact on motor function** seen in a clinical trial of ambulatory people with Duchenne
- Safety information gathered from **more than 150 clinical trial participants treated with ELEVIDYS***
- A **one-time treatment** with monitoring plan informed through **years of study**

*Safety information in non-ambulatory people is limited to 8 clinical trial participants.

IMPORTANT SAFETY INFORMATION (continued)

What is the most important information to know about ELEVIDYS?

Infusion-related reactions, including hypersensitivity and serious allergic reactions (anaphylaxis), have occurred during and after ELEVIDYS infusion. Symptoms may include fast heart rate, fast breathing, swollen lips, shortness of breath, nostrils widening, hives, red and blotchy skin, itchy or inflamed lips, rash, vomiting, nausea, chills, and fever. Your doctor will monitor you during and at least 3 hours after ELEVIDYS infusion. If an infusion-related reaction occurs, your doctor may slow or stop the ELEVIDYS infusion and provide additional medical treatment as needed. Contact a healthcare provider immediately if infusion-related symptoms occur.

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Understanding eligibility

Who is eligible for ELEVIDYS?

- ELEVIDYS is approved for people with Duchenne aged 4 years and up, regardless of ambulation. Use in non-ambulatory people was approved under accelerated approval, which allows for drugs to be approved based on a marker that is considered reasonably likely to predict a clinical benefit.

  Treatment with ELEVIDYS increased the marker, ELEVIDYS micro-dystrophin. Participation by non-ambulatory people was limited, and the impact on motor function was not studied in non-ambulatory people.

  Verification of clinical benefit may be needed for ELEVIDYS to continue to be approved for non-ambulatory people with Duchenne. Studies are ongoing to assess this potential impact.

Who determines eligibility?

- A doctor at a treatment center that administers ELEVIDYS will confirm eligibility.

What genetic mutations may be eligible?

- All mutations except for deletions in exons 8 and/or 9.* Patients with certain mutation deletions (in exons 1 to 17 and/or exons 59 to 71) may be at risk for a severe immune-mediated myositis reaction.

How is eligibility confirmed?

- A **genetic test** is required to confirm a mutation in the dystrophin gene. If you've had a test already, provide the report to your doctor to see if an updated test may be needed.

  An **antibody test** is required to measure preexisting antibodies to the ELEVIDYS vector, called AAVrh74. If the levels are too high, ELEVIDYS may not be an option.

  Your doctor will perform **additional tests** to confirm ELEVIDYS is appropriate.

*Duplication mutations in exons 8 and/or 9 are not contraindicated.

Thomas
Received treatment with ELEVIDYS

IMPORTANT SAFETY INFORMATION (continued)

What is the most important information to know about ELEVIDYS? (continued)

ELEVIDYS can increase certain liver enzyme levels and cause acute serious liver injury. Patients will receive oral corticosteroid medication before and after infusion with ELEVIDYS and will undergo weekly blood tests to monitor liver enzyme levels for 3 months after treatment. Contact a healthcare provider immediately if the patient's skin and/or whites of the eyes appear yellowish or if the patient misses a dose of corticosteroid or vomits it up.

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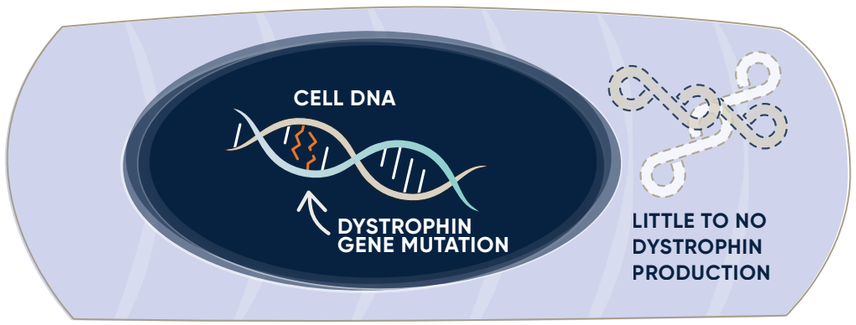
ELEVIDYS helps the body make a new version of dystrophin

In Duchenne, a genetic mutation, or change, in the dystrophin gene prevents the body from making dystrophin

- Without dystrophin, **muscles become damaged**
- Over time, people with **Duchenne lose muscle strength and the ability to perform everyday activities**

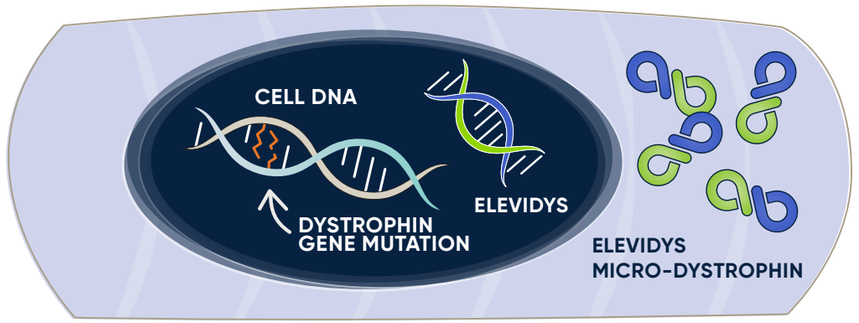


DUCHENNE MUSCLE CELL WITHOUT TREATMENT

Treatment that increases dystrophin is an important early step in a Duchenne treatment plan

ELEVIDYS delivers a gene that instructs the body to make a new, shorter version of dystrophin, called ELEVIDYS micro-dystrophin

- ELEVIDYS micro-dystrophin is similar to the body's natural dystrophin. While not exactly the same as dystrophin, it was designed to help protect muscles from damage.
- The gene **only needs to be delivered once** to do its job: once inside the body, it provides the instructions needed to **make ELEVIDYS micro-dystrophin**



DUCHENNE MUSCLE CELL WITH TREATMENT

To learn more about how ELEVIDYS works, visit ELEVIDYS.com.

IMPORTANT SAFETY INFORMATION (continued)

What is the most important information to know about ELEVIDYS? (continued)

Administration of ELEVIDYS may be delayed in patients who have acute liver disease until the condition is resolved or under control. Patients with preexisting liver impairment, chronic liver infection, or acute liver disease may be at higher risk of acute serious liver injury.

Please see additional Important Safety Information and full Prescribing Information.

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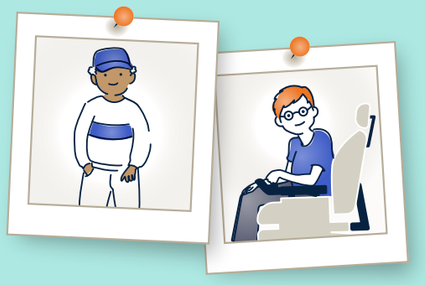
ELEVIDYS clinical trial program included more than 200 people across multiple trials

3-20 YEARS OLD*

AMBULATORY & NON-AMBULATORY†



RANGE OF GENETIC MUTATIONS‡

*ELEVIDYS is approved for individuals at least 4 years old with Duchenne.

†Safety information in non-ambulatory people is limited to 8 clinical trial participants.

‡ELEVIDYS cannot be used in anyone with a deletion in exon 8 and/or exon 9 in the dystrophin gene.

Andrew
Received treatment with ELEVIDYS

IMPORTANT SAFETY INFORMATION (continued)

What is the most important information to know about ELEVIDYS? (continued)

Immune-mediated myositis (an immune response affecting muscles) was observed in patients with a deletion mutation in the *DMD* gene that is contraindicated. Patients with certain mutation deletions (in exons 1 to 17 and/or exons 59 to 71) may be at risk for a severe immune-mediated myositis reaction. Caregivers should contact a healthcare provider immediately if the patient experiences any unexplained increased muscle pain, tenderness, or weakness, including difficulty swallowing, breathing, or speaking, as these may be symptoms of myositis.

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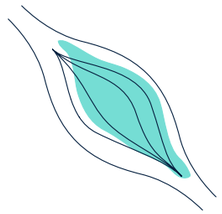
The clinical trials were designed to evaluate safety and efficacy

Results measured:

If ELEVIDYS micro-dystrophin was produced in skeletal muscles



If ELEVIDYS micro-dystrophin worked properly, measured through impact on muscle function

Safety, or what side effects people experienced after ELEVIDYS treatment

IMPORTANT SAFETY INFORMATION (continued)

What is the most important information to know about ELEVIDYS? (continued)

Myocarditis (inflammation of the heart) has been observed within days following ELEVIDYS infusion. The patient's doctor will conduct weekly blood tests for the first month after treatment to evaluate troponin-I (a cardiac protein that can detect damage to muscle cells in the heart). Caregivers should contact a healthcare provider immediately if the patient begins to experience chest pain and/or shortness of breath. More frequent monitoring may be required if the patient has cardiac symptoms.

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Trials measured results over time in a broad range of people

Study 1

- Placebo-controlled trial*
- 41 ambulatory participants
- Aged 4-7 years
- 2-part trial, with each part lasting 48 weeks

MAIN GOALS WERE TO MEASURE:

- ELEVIDYS micro-dystrophin
- Impact on muscle function
- Safety

Study 2 (also called "ENDEAVOR")

- Open-label trial†
- 48 participants
- Aged 3-20 years
- Included:
  - 40 ambulatory participants aged 3-12 years
  - 8 non-ambulatory participants aged 10-20 years

MAIN GOALS WERE TO MEASURE:

- ELEVIDYS micro-dystrophin
- Safety

Muscle function was not a main goal of this study

Study 3 (also called "EMBARK")

- Placebo-controlled trial*
- 125 ambulatory participants
- Aged 4-7 years
- 2-part trial, with each part lasting 52 weeks. Results from Part 1 are shared in this brochure

MAIN GOALS WERE TO MEASURE:

- Impact on muscle function
- Safety

*A placebo-controlled trial includes the medication being studied and a placebo, a substance that has no active medication. Results are then compared.

†In an open-label trial, all participants know that they are taking the medication being studied.

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Across all trials, participants produced an average of 34%-51% ELEVIDYS micro-dystrophin

Average increase in ELEVIDYS micro-dystrophin 3 months after treatment

AMBULATORY PARTICIPANTS

Study 1
PART 1

↑43%

6 participants

Study 1
PART 2

↑41%

21 participants

Study 2

↑51%

40 participants

Study 3
PART 1

↑34%

17 participants

In Study 3, since people receiving placebo (14 participants) did not receive ELEVIDYS, they had 0% ELEVIDYS micro-dystrophin

HOW DID IT WORK?

Results were measured using **a test called a western blot,** which looks at a small piece of muscle from a person's body to see **if micro-dystrophin was produced**. The numbers reflect the amount produced, compared to the start of the trial, if 100% was the typical level in a person without Duchenne.

Average increase in ELEVIDYS micro-dystrophin 3 months after treatment

NON-AMBULATORY PARTICIPANTS

Study 2

↑40%

8 participants

People with Duchenne typically have **little to no dystrophin**

IMPORTANT SAFETY INFORMATION (continued)

What is the most important information to know about ELEVIDYS? (continued)

Patients need to have blood tests to ensure that they do not have antibodies that may prevent them from being able to receive ELEVIDYS, as introducing the gene therapy could increase the risk of a severe allergic reaction or prevent desired therapeutic levels. Treatment with ELEVIDYS is not recommended for patients who have high antibodies to the vector, the part of gene therapy used to deliver ELEVIDYS.

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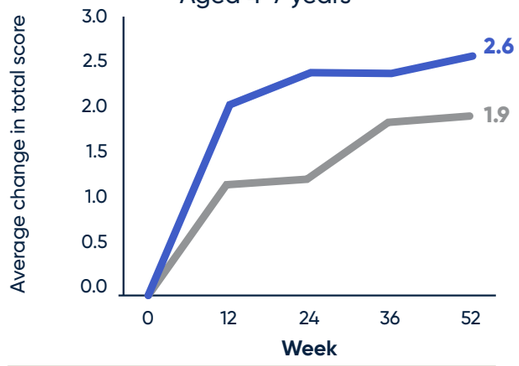
Impact on motor function, as measured by North Star Ambulatory Assessment (NSAA)

The NSAA is a broad measure used to monitor overall ambulatory function over time. Study 3 participants treated with ELEVIDYS scored 0.7 points higher, on average, than those who received placebo after 1 year. The difference was not statistically significant.

Average change in NSAA score 1 year after treatment

Study 3, Part 1

Aged 4-7 years



ELEVIDYS	63	61	63	61	63
Placebo	62	62	60	61	61

To learn more about NSAA, visit ELEVIDYS.com

Similar results were seen in Study 1 when measured 48 weeks after treatment in participants aged 4 to 7 years: those who received ELEVIDYS (20 participants) scored 0.8 points higher, on average, than those who received placebo (no ELEVIDYS, 21 participants). The difference was not statistically significant.

All participants were on stable doses of steroids at the start of the trial regardless of whether they received ELEVIDYS or placebo.

IMPORTANT SAFETY INFORMATION (continued)

What is the most important information to know about ELEVIDYS? (continued)

Due to the need to follow a corticosteroid regimen, an infection (such as cold, flu, gastroenteritis [stomach flu], otitis media [ear infection], bronchiolitis [respiratory infection], etc) before or after ELEVIDYS infusion could lead to more serious complications. Caregivers should contact a healthcare provider immediately if they see any symptoms suggestive of infection, such as coughing, wheezing, sneezing, runny nose, sore throat, or fever.

Are there any considerations for vaccination schedules and ELEVIDYS?

Patient vaccinations should be up to date with current immunization guidelines. Vaccinations should be received at least 4 weeks prior to starting the corticosteroid regimen that is required before receiving ELEVIDYS.

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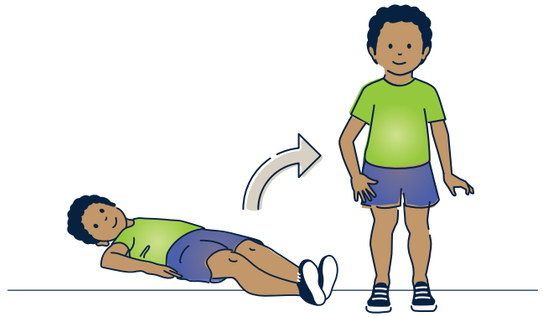
ELEVIDYS improved participants' speed on the time to rise from floor test



Study 3, Part 1

Average change in time to rise from floor from start of trial to 1 year

124 participants aged 4–7 years

Participants who received ELEVIDYS *(63 people)*

0.27 seconds

faster

vs start of trial

Participants who received placebo *(61 people)*

0.37 seconds

slower

vs start of trial

Those who received ELEVIDYS were able to get up from the floor

0.64 seconds faster

than those on placebo (no ELEVIDYS) after 1 year (on average)

HOW DID IT WORK?

At the start of the trial, **participants were asked to stand up from lying on their backs as quickly as they could,** and these times were recorded. Half the participants then received ELEVIDYS and the other half received placebo (no ELEVIDYS). **One year later, everyone repeated the test** to see if their results changed from the start of the trial. While results varied across participants, the average difference is noted above.

All participants were on stable doses of steroids at the start of the trial regardless of whether they received ELEVIDYS or placebo.

IMPORTANT SAFETY INFORMATION (continued)

Are there any precautions that need to be considered when handling a patient's bodily waste?

Vector shedding of ELEVIDYS occurs primarily through body waste. Patients and caregivers should use proper hand hygiene, such as hand washing when coming into direct contact with patient body waste. Place potentially contaminated materials that may have the patient's bodily fluids/waste in a sealable bag and dispose into regular trash. Precautions should be followed for 1 month after ELEVIDYS infusion.

What are the possible or likely side effects of ELEVIDYS?

The most common side effects that occurred in patients treated with ELEVIDYS were vomiting, nausea, liver injury, fever, and decreased platelet counts.

Please see additional Important Safety Information and full Prescribing Information.

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Participants treated with ELEVIDYS could walk/run faster on a test of motor function

Study 3, Part 1

Average change in 10-meter walk/run time from start of trial to 1 year

124 participants aged 4-7 years

Participants who received ELEVIDYS *(63 people)*
0.34 seconds
faster
vs start of trial

Participants who received placebo *(61 people)*
0.08 seconds
slower
vs start of trial

Those who received ELEVIDYS were able to walk/run 10 meters

0.42 seconds faster

than those on placebo (no ELEVIDYS) after 1 year (on average)

HOW DID IT WORK?

At the start of the trial, **participants were asked to run or walk 10 meters (approximately 30 feet) as quickly as they could,** and these times were recorded. Half the participants then received ELEVIDYS and the other half received placebo (no ELEVIDYS). **One year later, everyone repeated the test** to see if their results changed from the start of the trial. While results varied across participants, the average difference is noted above.

All participants were on stable doses of steroids at the start of the trial regardless of whether they received ELEVIDYS or placebo.

IMPORTANT SAFETY INFORMATION (continued)

What are the possible or likely side effects of ELEVIDYS? (continued)

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.

Who should not receive ELEVIDYS?

Individuals with certain types of mutations, any deletion in exon 8 and/or exon 9 in the *DMD* gene, should not receive ELEVIDYS.

What is the most important information to know about ELEVIDYS?

Infusion-related reactions, including hypersensitivity and serious allergic reactions (anaphylaxis), have occurred during and after ELEVIDYS infusion. Symptoms may include fast heart rate, fast breathing, swollen lips, shortness of breath, nostrils widening, hives, red and blotchy skin, itchy or inflamed lips, rash, vomiting, nausea, chills, and fever. Your doctor will monitor you during and at least 3 hours after ELEVIDYS infusion. If an infusion-related reaction occurs, your doctor may slow or stop the ELEVIDYS infusion and provide additional medical treatment as needed. Contact a healthcare provider immediately if infusion-related symptoms occur.

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Important Safety Information

What is ELEVIDYS?

ELEVIDYS is a prescription gene therapy used to treat ambulatory individuals at least 4 years old with Duchenne muscular dystrophy (DMD) who have a confirmed mutation in the *DMD* gene.

ELEVIDYS is approved under accelerated approval for non-ambulatory patients at least 4 years old with DMD who have a confirmed mutation in the *DMD* gene. Accelerated approval allows for drugs to be approved based on a marker that is considered reasonably likely to predict a clinical benefit. ELEVIDYS treatment increased the marker, ELEVIDYS micro-dystrophin in skeletal muscle. Verification of a clinical benefit may be needed for ELEVIDYS to continue to be approved for non-ambulatory patients with DMD.

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ELEVIDYS can increase certain liver enzyme levels and cause acute serious liver injury. Patients will receive oral corticosteroid medication before and after infusion with ELEVIDYS and will undergo weekly blood tests to monitor liver enzyme levels for 3 months after treatment. Contact a healthcare provider immediately if the patient's skin and/or whites of the eyes appear yellowish or if the patient misses a dose of corticosteroid or vomits it up.

Administration of ELEVIDYS may be delayed in patients who have acute liver disease until the condition is resolved or under control. Patients with preexisting liver impairment, chronic liver infection, or acute liver disease may be at higher risk of acute serious liver injury.

Immune-mediated myositis (an immune response affecting muscles) was observed in patients with a deletion mutation in the *DMD* gene that is contraindicated. Patients with certain mutation deletions (in exons 1 to 17 and/or exons 59 to 71) may be at risk for a severe immune-mediated myositis reaction. Caregivers should contact a healthcare provider immediately if the patient experiences any unexplained increased muscle pain, tenderness, or weakness, including difficulty swallowing, breathing, or speaking, as these may be symptoms of myositis.

Myocarditis (inflammation of the heart) has been observed within days following ELEVIDYS infusion. The patient's doctor will conduct weekly blood tests for the first month after treatment to evaluate troponin-I (a cardiac protein that can detect damage to muscle cells in the heart). Caregivers should contact a healthcare provider immediately if the patient begins to experience chest pain and/or shortness of breath. More frequent monitoring may be required if the patient has cardiac symptoms.

What is the most important information to know about ELEVIDYS? (continued)

Patients need to have blood tests to ensure that they do not have antibodies that may prevent them from being able to receive ELEVIDYS, as introducing the gene therapy could increase the risk of a severe allergic reaction or prevent desired therapeutic levels. Treatment with ELEVIDYS is not recommended for patients who have high antibodies to the vector, the part of gene therapy used to deliver ELEVIDYS.

Due to the need to follow a corticosteroid regimen, an infection (such as cold, flu, gastroenteritis [stomach flu], otitis media [ear infection], bronchiolitis [respiratory infection], etc) before or after ELEVIDYS infusion could lead to more serious complications. Caregivers should contact a healthcare provider immediately if they see any symptoms suggestive of infection, such as coughing, wheezing, sneezing, runny nose, sore throat, or fever.

Are there any considerations for vaccination schedules and ELEVIDYS?

Patient vaccinations should be up to date with current immunization guidelines. Vaccinations should be received at least 4 weeks prior to starting the corticosteroid regimen that is required before receiving ELEVIDYS.

Are there any precautions that need to be considered when handling a patient's bodily waste?

Vector shedding of ELEVIDYS occurs primarily through body waste. Patients and caregivers should use proper hand hygiene, such as hand washing when coming into direct contact with patient body waste. Place potentially contaminated materials that may have the patient's bodily fluids/waste in a sealable bag and dispose into regular trash. Precautions should be followed for 1 month after ELEVIDYS infusion.

What are the possible or likely side effects of ELEVIDYS?

The most common side effects that occurred in patients treated with ELEVIDYS were vomiting, nausea, liver injury, fever, and decreased platelet counts.

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 negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Sarepta Therapeutics at 1-888-SAREPTA (1-888-727-3782).

Please see full Prescribing Information for ELEVIDYS.

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Safety information from more than 150 people

Across all trials, 5 common side effects occurred in 5% or more participants

Side effect	ELEVIDYS N=156
Vomiting	65%
Nausea	43%
Liver injury	40%
Fever	28%
Low platelet count	8%

The same common side effects were seen in Study 3 when compared with the placebo group

Side effect	ELEVIDYS n=63	Placebo n=62
Vomiting	64%	19%
Nausea	40%	13%
Liver injury	41%	8%
Fever	32%	24%
Low platelet count	3%	0%

- Safety information in non-ambulatory people is limited to 8 clinical trial participants
- To help reduce the likelihood of side effects, treatment-related steroids are required 1 week before infusion (if not already taking steroids) or 1 day before infusion (if already on a steroid regimen). These steroids will continue for at least 2 months after treatment
- These are the most common side effects. Talk to your child's doctor about all the possible side effects of ELEVIDYS

Please see additional Important Safety Information and full Prescribing Information.

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Monitoring plan specifically designed for support after treatment

People treated with ELEVIDYS are monitored weekly for at least 3 months to support their well-being.

Your doctor will order blood tests to monitor **liver function** (weekly for the first 3 months); **platelet counts** (weekly for the first 2 weeks); and **troponin-I levels** (weekly for the first month). More frequent monitoring may be required.

To help reduce the risk of side effects, your child will need to take treatment-related steroids. Your child will start these shortly before the infusion day and will continue for at least 2 months.*

TREATMENT DAY

The care team at the treatment center will closely watch for any infusion-related reactions for at least 3 hours after treatment

DURING THE FIRST 2 WEEKS

The most common side effects, which typically occur in the **first 2 weeks**, include vomiting (as early as on infusion day), nausea, fever, and low platelet count

DURING THE FIRST 2 MONTHS

Side effects that could occur within the **first 2 months** include:

- An immune response affecting muscles (immune-mediated myositis)
- Inflammation of the heart (myocarditis)
- Liver injury (there were no cases of liver failure in the clinical trials)

DURING THE FIRST 3 MONTHS

Liver function will continue to be monitored for at least 3 months

In clinical trials, most side effects occurred within 2 months of treatment, but it is recommended that people treated with ELEVIDYS are monitored for 3 months or longer, if needed

*Your doctor may adjust this length of time — or the dose — based on the person's response to ELEVIDYS, including helping address any changes in liver function tests. It's important to follow your doctor's advice on ELEVIDYS treatment-related steroids, including during the tapering period.

IMPORTANT SAFETY INFORMATION (continued)

What is the most important information to know about ELEVIDYS? (continued)

ELEVIDYS can increase certain liver enzyme levels and cause acute serious liver injury. Patients will receive oral corticosteroid medication before and after infusion with ELEVIDYS and will undergo weekly blood tests to monitor liver enzyme levels for 3 months after treatment. Contact a healthcare provider immediately if the patient's skin and/or whites of the eyes appear yellowish or if the patient misses a dose of corticosteroid or vomits it up.

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ELEVIDYS offers a different path forward

ELEVIDYS has been studied in more than 200 clinical trial participants.* However, as the progression of Duchenne is different for each person, **it can be helpful to speak to your doctor about what to expect from treatment** based on your starting point

- Sharing what you or your child can do now will help **create a baseline to use to track progress**

Explore ELEVIDYS family stories at ELEVIDYS.com

*Safety information in non-ambulatory people is limited to 8 clinical trial participants.

IMPORTANT SAFETY INFORMATION (continued)

What is the most important information to know about ELEVIDYS? (continued)

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Celebrate this moment

The only FDA-approved gene therapy for Duchenne

SAREPTASSIST

SUPPORT, BY YOUR SIDE

The SareptAssist team is available 1-888-SAREPTA (1-888-727-3782) Monday through Friday, 8:30am — 6:30pm ET

Spanish-speaking Case Managers and interpreters for other languages are also available.

IMPORTANT SAFETY INFORMATION (continued)

What is the most important information to know about ELEVIDYS? (continued)

Immune-mediated myositis (an immune response affecting muscles) was observed in patients with a deletion mutation in the *DMD* gene that is contraindicated. Patients with certain mutation deletions (in exons 1 to 17 and/or exons 59 to 71) may be at risk for a severe immune-mediated myositis reaction. Caregivers should contact a healthcare provider immediately if the patient experiences any unexplained increased muscle pain, tenderness, or weakness, including difficulty swallowing, breathing, or speaking, as these may be symptoms of myositis.

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SAREPTA THERAPEUTICS

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