

GETTING STARTED

with ELEVIDYS
(delandistrogene moxeparvovec-rokl)

Your guide to the insurance process and the next chapter in your child's Duchenne muscular dystrophy (DMD) gene therapy treatment journey



Jaylen
Received treatment
with ELEVIDYS

Important Safety Information

What is ELEVIDYS (delandistrogene moxeparvovec-rokl)?

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 the additional Important Safety Information on pages 17 and 18 and the full [Prescribing Information](#) for ELEVIDYS.

 **Elevidys**
delandistrogene
moxeparvovec-rokl
suspension for intravenous infusion



What's inside?

Welcome! This is an important time in your child's Duchenne journey as you prepare for treatment with ELEVIDYS, and getting approval from your insurance company to help cover the costs of gene therapy can require multiple steps.

This guide can help you navigate the insurance process.

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TIP!

SareptAssist is with you every step of the way as you get started with ELEVIDYS.

Reach out to us directly with any questions at 1-888-SAREPTA (1-888-727-3782) Monday through Friday, 8:30 AM – 6:30 PM ET.

Types of insurance

Health insurance can help pay for some of your ELEVIDYS treatment. The amount and types of costs covered **vary depending on the type of insurance you have**.

Private (commercial) and public (government) are the most common types of health insurance.



Private or commercial

Private or commercial insurance can be offered through an employer or by purchasing it directly from an insurance company or state insurance exchange.

Employers may offer a variety of plans during their **open enrollment period**, and each plan may vary in coverage, costs, and out-of-pocket expenses.

Knowing the type of plan your employer has can help you understand the type of coverage offered. Reach out to your employer's human resources department or refer to materials such as an employee handbook for more information on your plan.



Public or government-sponsored

Public or government-sponsored plans are provided at the federal and state level for people who qualify for assistance.

Medicaid and Medicare are common types of public insurance that provide health coverage to millions of Americans.

Federal law requires states to provide Medicaid coverage to certain groups of individuals, including (but not limited to):

- Low-income families*
- Qualified pregnant women and children
- Individuals receiving Supplemental Security Income

Dual eligibility applies to individuals who receive medical coverage from both Medicare and Medicaid.

Some patients may be eligible for Medicaid as secondary insurance, meaning that Medicaid will be the payer of last resort for costs not covered by their commercial insurance.

*Based on federal poverty guidelines published in January of each year. Note, guidelines vary by family size. In addition, there is one set of figures for the 48 contiguous states and Washington, DC; one set for Alaska; and one set for Hawaii.
<https://aspe.hhs.gov/topics/poverty-economic-mobility/poverty-guidelines>

CHAPTER
1

Medicaid and Medicare

People with Duchenne may be covered by Medicaid or Medicare. Below are important facts about these programs to help you understand the differences. **Your SareptAssist Case Manager can share information with you about the different programs and how to enroll.**

Medicaid is a joint federal and state insurance program that covers millions of people, including:

- Low-income households
- Children
- Elderly adults
- Adults
- Pregnant women
- People with disabilities

Medicaid is administered by states according to federal requirements. You may hear the terms **Medicaid fee-for-service** or **Medicaid Managed Care**. If you are enrolled in Medicaid fee-for-service, that means the state pays healthcare providers directly for health services. If you are enrolled in a Medicaid Managed Care program, that means you are part of a healthcare plan. In this case, the state pays the plan, and the plan then pays providers for services.

All Medicaid programs provide coverage for prescription medications, typically at the lowest cost to beneficiaries.

Medicare offers health insurance for people:

- Aged 65 years and older
- Under age 65 who have certain disabilities
- Of all ages with end-stage renal disease and amyotrophic lateral sclerosis (ALS)

Within Medicare, there are different parts that cover different healthcare needs, such as:



Patients over the age of 20 with Duchenne qualify for Medicare after receiving **Social Security Disability Insurance** benefits for at least 2 years. For more information about how to qualify for Medicare, visit SSA.gov.

*This is a managed care plan that offers both Medicare Parts A and B benefits and other supplemental benefits that may not be offered by traditional Medicare fee-for-service plans.



There are also special federal and state programs that cover the costs associated with Duchenne. For example, in addition to Medicaid and Medicare, people may be covered by the Children’s Health Insurance Program (CHIP) or may qualify for disability benefits. Look to page 5 for details.

Special federal and state programs

People with Duchenne may automatically qualify for one or more of these special federal or state programs that may **cover costs of drug infusions, transportation, hospital care, doctor visits, and home healthcare**. It's important to know about them and how to enroll. Your SareptAssist Case Manager can help.



Supplemental Security Income or Social Security Disability

Each state has different qualification requirements for Medicaid coverage. Children with Duchenne may be eligible for Social Security Administration (SSA) benefits through the Supplemental Security Income or Social Security Disability Insurance programs—which means they may qualify for Medicaid.



Children's Health Insurance Program (CHIP)

CHIP is a joint federal-state program offering **free or low-cost coverage for uninsured children and teens under 19 years of age** in families with incomes too high to qualify for Medicaid.



Compassionate Allowances

The SSA Compassionate Allowances (CAL) program is available for adults with Duchenne. This program identifies severe medical diseases, including Duchenne, that automatically meet SSA standards for disability benefits, and **fast tracks the Medicaid application process**. Today, there are more than 250 conditions on the list.



Medicaid or a Katie Beckett waiver (available in some states)

These are expanded programs that some states may offer to certain groups of people, based on different criteria in each state. **These waiver programs often provide coverage for families of children with exceptional health needs that may otherwise not qualify for Medicaid, and often help them remain home for health services.**



Visit [Medicaid.gov](https://www.Medicaid.gov) to learn more about Medicaid programs in your state. You can also ask your SareptAssist Case Manager about which programs may be best for you.

CHAPTER
1

How costs are covered

Whichever type of plan you have (eg, private or public), your insurance company **may share some of the costs of ELEVIDYS with you**. Here are some of the costs that you may be responsible for:



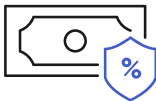
Premium

Amount you pay to participate in the health plan, which will vary depending on the plan and type of coverage you select (eg, individual, couple, family). You may be responsible for these costs biweekly, monthly, quarterly, or annually.



Deductible

Set amount you pay each year before the plan covers a portion of the costs.



Co-insurance

Percentage of a medical charge you pay after you've received healthcare services. Typically, co-insurance is a fixed percentage, meaning you'll always be charged the same percentage (eg, 20%) of the total bill each time.



Co-pay

In addition to the deductible, you may be required to pay a co-pay—or specific dollar amount—for every doctor visit or medication. This amount will be less than the deductible and is typically a fixed cost.

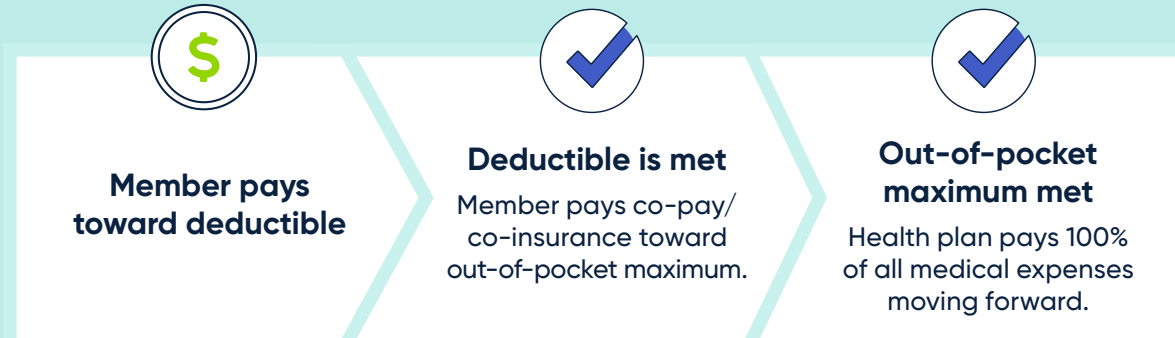
The Affordable Care Act set a maximum limit for the amount health plan members have to pay in out-of-pocket expenses. This limit applies to your deductible, co-insurance, or co-pay. These limits vary by plan and type of health service (eg, in-network vs out-of-network).



How does your plan cover costs? Knowing the terms deductible, co-insurance, and co-pay can help you understand your out-of-pocket expenses for Duchenne treatment.

CHAPTER
1

How does a deductible work?



To give you an example:

Let's say your deductible is \$2000	\$2000
You go to the doctor with abdominal pain and pay \$100 for the office visit	-\$100
You still have \$1900 more to reach your deductible	\$1900
You pay for an X-ray your doctor orders	-\$500
You still have \$1400 to reach your deductible	\$1400
Based on the X-ray, your doctor recommends surgery that costs \$2000 You pay the \$1400 left of your deductible	-\$1400
Your remaining deductible is now \$0	\$0
The health insurance plan pays the remaining \$600	\$600
Your doctor recommends a series of follow-ups and since you have met your deductible, you are only responsible for the co-pay amounts at your appointments (related or unrelated to an ongoing health issue) for the rest of the calendar year	Pay co-pay amount

Deductible
 Paid by you
 Paid for by your health insurance plan

Many plans pay for certain services, such as checkups or disease management programs, before you have met your deductible. Check your plan details.

Please see the Important Safety Information on pages 17 and 18 and the full [Prescribing Information](#) for ELEVIDYS.

ELEVIDYS[®] (delandistrogene moxeparvovec-rokl) is a specialty medication

ELEVIDYS requires special care and is distributed through a specialty pharmacy to ensure it is handled safely.



Specialty medications may have special storage requirements or involve infusions or injections.

Depending on the plan, specialty products may be covered under the medical benefit. Both private and public insurance offer medical benefits.



Medical benefit often covers procedures or care received in a hospital or at a doctor's office.

Medications administered in an outpatient setting (eg, home, hospital, doctor's office, freestanding infusion clinic) may incur additional costs for the visit.



TIP!

Infusions that occur in the outpatient setting, such as ELEVIDYS, are usually covered under the medical benefit, whereas home infusions can be covered under either the pharmacy or medical benefit, depending on your plan.



CHAPTER
1

Sample bill

You may receive an **explanation of benefits (EOB)** that looks like a bill. An EOB is not a bill—it helps you understand what your health plan covers and what you'll need to pay when you do receive a bill. If you have any questions, reach out to your SareptAssist Case Manager.

We have provided a sample bill with important information you should look out for. Note that your actual bill may look different from the example provided below.

Hospital outpatient service sample bill

MAKE CHECKS PAYABLE TO:

IF PAYING BY CREDIT CARD, PLEASE FILL OUT BELOW

CHECK CARD TO BE USED FOR PAYMENT

CARD NUMBER	AMOUNT
SIGNATURE	EXP. DATE

INVOICE DATE	PLEASE PAY THIS AMOUNT	ACCOUNT NUMBER
09/2/04	\$100.00	123456789

PATIENT NAME
Susan A. Patient

PAYMENT IS DUE UPON RECEIPT.
 Please check box if address is incorrect or insurance information has changed, indicate change(s) on reverse side.

0000 0000000111111111 0159275 0000000 0000000000 4

INVOICE PLEASE DETACH AND RETURN TOP PORTION WITH YOUR PAYMENT.

Thursday, September 2, 2004

Patient: Susan A. Patient
Account: 123456789
Amount Due: \$100.00

Date of Service: 04/24/04
Patient Service: ER Arena
Primary Insurance Billed: WPS
Secondary Insurance Billed: Blue Cross

Dear Susan:

Thank you for selecting [redacted] for your health care services. For your records, below is a summary of the charges for this account. If you would like an itemized statement, please call Patient Financial Services at [redacted]

Pharmacy	\$ 28.40
Emergency Room	\$ 947.00
EKG/ECG	\$ 84.00
Total Charges	\$ 1,059.40
Total Payments	\$ -815.74
Total Adjustments	\$ -143.66
Please Pay This Amount	\$ 100.00

Please mail payment in full today or contact Patient Financial Services at [redacted] to arrange payment. Please visit us at <http://billpay> if you would like to make a payment online using MasterCard, Visa or Discover or if you would like to view a list of Frequently Asked Questions.

Sincerely,
Patient Financial Services

Page 1 of 1

You can pay your bill by check or credit card

Use this number whenever referring to this bill

Services include all hospital-provided care, testing, and/or treatment(s)

This is the current summary of total hospital charges on this account

This shows the total payment made by your health insurance

The adjustment reflects the amount the hospital has agreed not to charge

This is your balance due as of the above invoice date

Use this number for questions regarding this account



CHAPTER
1

Drug formularies and prior authorization

What is a formulary?

Most health plans have a **formulary as part of their pharmacy benefit**. The formulary is a list of prescription drugs that is grouped into different categories or tiers and helps determine the cost of the drug. The amount you may have to pay for the drug is determined by the tier level. Typically, a drug formulary includes **4 or 5 tiers**. Here's an example of a typical tier structure:

TIER 1	Generic or lowest cost drugs, including some corticosteroids	These treatments are covered by the pharmacy benefit and can either be taken at home or administered at a provider's office.
TIERS 2-3	Brand-name drugs or more expensive generics	
TIER 4	More expensive brand-name drugs	
TIER 5	Specialty drugs such as infusions or the most expensive medications	Some specialty drugs administered by a provider or in the outpatient setting are covered by the medical benefit . Out-of-pocket costs may differ depending on whether a drug is covered under the pharmacy or medical benefit.

What is a prior authorization?

ELEVIDYS may require a prior authorization, which is a process that health plans use to ensure the drug is being used appropriately and to better control the use of more expensive medications.

If your health plan requires a prior authorization, it means that your doctor must submit documentation explaining why ELEVIDYS is necessary before the plan will cover it. **Prior authorization requirements vary by plan.**



Your doctor, their office staff, and your SareptAssist Case Manager can help guide you through the prior authorization process. Read on to learn more.

Your care team will be with you every step of the way

Once you and your doctor decide that ELEVIDYS is right for you or your family member, Sarepta has resources that can help you navigate the complexities of accessing treatment. The process is different for everyone. It varies due to many factors, such as the type of insurance you have, your treatment needs, and financial assistance options. It will be important to get to know your healthcare team, who will be your partners in your treatment journey and can help you with your specific situation.



Get to know your care team

At the
doctor or
clinic

Doctor: confirms your eligibility for ELEVIDYS, prescribes medication, and provides medical care.

Nurse: provides care, administers medication.

Office Staff: handles appointments and administrative issues such as billing and payments; assists with prior authorizations and appeals to help patients get access to medications.

At the
health
plan

Member Services: handles insurance policy questions and claims processing.

Medical Director: responsible for helping to build formularies and reviewing prior authorizations and appeals.

Your
Sarepta
team

SareptAssist Case Manager: one of your key contacts for questions about your insurance benefits, treatment delivery, and access to medication.

Patient Access Manager (PAM): works with you and your SareptAssist Case Manager to navigate the denial and appeals process.

Director Market Access and Reimbursement (DMAR): provides access and reimbursement support for doctors' offices and insurance companies.

Duchenne Nurse Educator (DNE): provides training for drug administration; answers general questions you may have about ELEVIDYS and/or the infusion process.

Specialty
pharmacy/
drug
distributor

Pharmacist: coordinates medication shipment, reviews physician orders, and consults with families if needed.

Nurse/Coordinator: facilitates contracts/appointments with home health agencies.

Dedicated Care Team: coordinates medication shipment to site or home, ships necessary supplies, and assists with home healthcare coordination.

Important steps in accessing ELEVIDYS

Once your doctor has submitted a Sarepta Gene Therapy Enrollment Form, there are **5 key steps to gain access** to the product and start therapy. Your SareptAssist Case Manager will be with you every step of the way.

1

Submit enrollment form

Your doctor will complete and submit the Sarepta Gene Therapy Enrollment Form, which will begin the SareptAssist process. Your SareptAssist Case Manager will reach out to welcome you and explain how they can help.

2

Benefits investigation

This process determines the type of insurance you have and the expected coverage it provides for ELEVIDYS, including prior authorization policies and out-of-pocket expenses. The prior authorization process often involves an appeal and extra time. **Your SareptAssist Case Manager will work with you to help you understand your specific insurance benefits and next steps.**

3

Treatment location

You will receive treatment at a hospital where you will have direct support from healthcare providers who specialize in administering ELEVIDYS. Sarepta partners with hospital institutions in advance of treatment to ensure they are prepared for ELEVIDYS and have the necessary steps in place to facilitate infusion.

4

Starting treatment

Once your insurance benefits have been confirmed and you have received approval for infusion, **your Sarepta team will work closely with you and your healthcare provider to schedule treatment and coordinate delivery logistics.** This process will vary based on your insurance provider and treatment location. Your Duchenne Nurse Educator will then guide your healthcare team through the drug administration process.

5

Ongoing support

Your SareptAssist Case Manager will work with you throughout your treatment journey. Following treatment, they will contact you with reminders of key postinfusion follow-up visits and lab work. They will continue to check in with you periodically and offer support as long as it is needed.



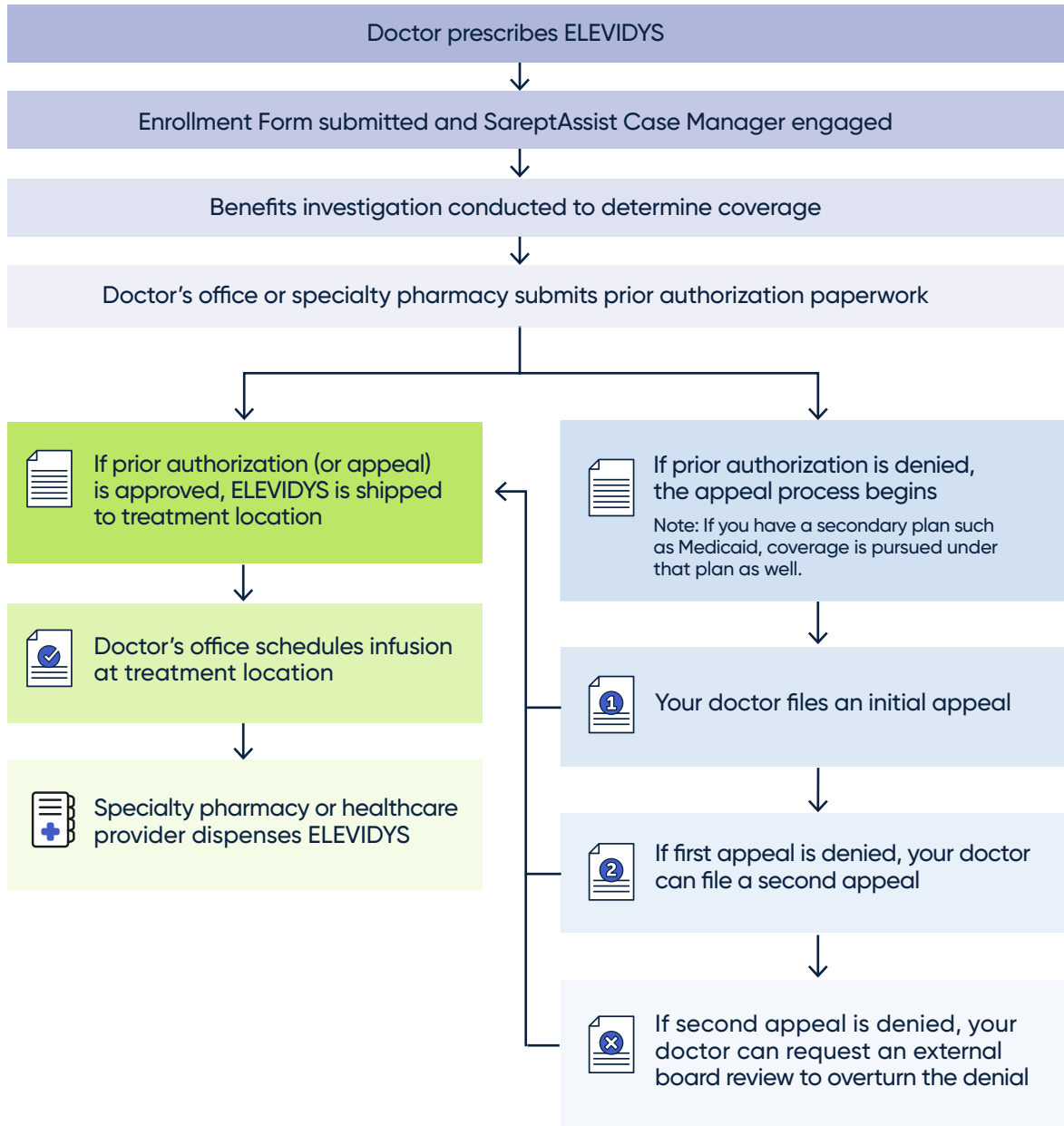
TIP!

Contact your SareptAssist Case Manager if you have any questions. Always reach out to your doctor before making any decisions about your Duchenne treatment.

CHAPTER
2

Benefits investigation: Duchenne medication authorization process

The first major step in accessing ELEVIDYS is obtaining a prior authorization from your insurance company. This can be a long and difficult process, but your SareptAssist Case Manager will be there to help you from the beginning. To better understand what typically happens during the authorization process, a brief overview has been provided below.



Common reasons for denials



Why is a prior authorization denied?

There are a number of reasons why a prior authorization may be denied for ELEVIDYS. Common ones include:

- Medication is only covered for a specific age range
- Incomplete information was provided, such as lack of proper clinical assessments
- The patient has not been on a treatment regimen of steroids
- Drug is excluded from coverage
- ELEVIDYS is not considered medically necessary based on the plan's specific criteria



What can you do?

You are a critical part of your own healthcare team. Actions you can take while going through the benefits investigation process include:

- Calling your SareptAssist Case Manager at 1-888-SAREPTA (1-888-727-3782) Monday through Friday, 8:30 AM–6:30 PM ET. Spanish-speaking team members and interpreters for other languages are also available
- Contacting your insurance company directly with questions about coverage
- Sharing any communication you may receive from your insurer with your SareptAssist Case Manager and your doctor's office
- Checking in regularly with your doctor's office or office staff at your infusion center
- Following up with scheduled clinical appointments with your doctor's office for necessary evaluations
- Reaching out to patient advocacy organizations for assistance
- Sharing your experiences

Financial assistance options

Depending on the type of insurance you have and other relevant circumstances, you may qualify for financial assistance programs. Your SareptAssist Case Manager can help provide information about the options and see if you are eligible for the following Sarepta programs.



Patient co-pay assistance program

This program may help with some out-of-pocket costs for ELEVIDYS (not the costs of supplies or other treatment-related costs). It is for eligible individuals in the United States with commercial insurance only, not government insurance, such as Medicaid, who are prescribed treatment with a Sarepta product.

Speak with your SareptAssist Case Manager about which financial assistance options may be best for you based on your needs.



Multiple independent charitable organizations

There are multiple programs that offer financial assistance, such as the Duchenne Family Assistance Program.

Your SareptAssist Case Manager can provide more information and direct you to these third-party options.



You can rely on your SareptAssist Case Manager and the other members of your care team to stay informed of your options and navigate your treatment journey as your needs change (eg, new insurance, change of address).

How Sarepta can help

SareptAssist, our patient support program, is designed to provide you with information to navigate the treatment process.

Our dedicated team will provide information on:

- Understanding the requirements for treatment
- Insurance benefits
- Financial assistance options
- One-time treatment logistics
- Ongoing education and support



Remember, while your doctor is your first point of contact for all medical needs, your **SareptAssist Case Manager** is committed to working with you during the treatment journey and will check in regularly.

For more information, visit [SareptAssist.com](https://www.sarepta.com/sareptassist).



We are committed to partnering with you, your doctors, and your health plan to help you access ELEVIDYS so you can focus on the next chapter.

Important Safety Information

What is ELEVIDYS (delandistrogene moxeparvovec-rokl)?

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.

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.

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.

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.

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 the additional Important Safety Information on page 17 and the full Prescribing Information for ELEVIDYS.

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