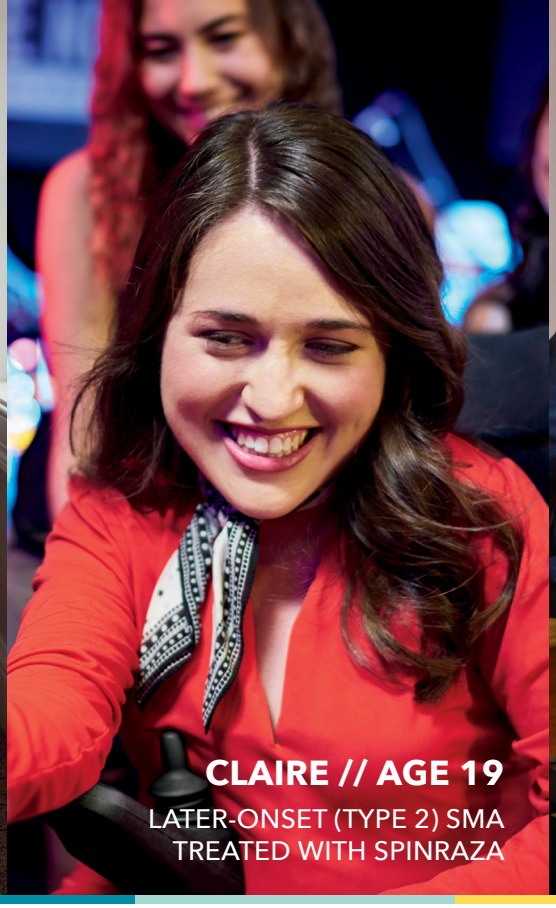

Individual results may vary based on several factors, including severity of disease, initiation of treatment, and duration of therapy.

NAVIGATING COVERAGE, ACCESS, AND SUPPORT FOR SPINRAZA® (nusinersen)

A GUIDE FOR PATIENTS WITH SPINAL MUSCULAR ATROPHY AND THEIR CAREGIVERS

INDICATION

SPINRAZA® (nusinersen) is a prescription medicine used to treat spinal muscular atrophy (SMA) in pediatric and adult patients.

SELECTED IMPORTANT SAFETY INFORMATION

Increased risk of bleeding complications has been observed after administration of similar medicines. Your healthcare provider should perform blood tests before you start treatment with SPINRAZA and before each dose to monitor for signs of these risks. Seek medical attention if unexpected bleeding occurs.

Please see additional Important Safety Information on page 44 and accompanying full Prescribing Information.

CLICK TO PRINT

SPINRAZA® (nusinersen) injection 12 mg/5 mL

SPINRAZA® (nusinersen) injection 12 mg/5 mL

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SELECTED IMPORTANT SAFETY INFORMATION

Increased risk of kidney damage, including potentially fatal acute inflammation of the kidney, has been observed after administration of similar medicines. Your healthcare provider should perform urine testing before you start treatment with SPINRAZA and before each dose to monitor for signs of this risk.

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SPINRAZA® (nusinersen) injection 12 mg/5 mL

WELCOME TO THE SPINRAZA® (nusinersen) PATIENT AND CAREGIVER INSURANCE GUIDE

Facing a diagnosis of spinal muscular atrophy (SMA) can feel overwhelming. No matter where you or your loved one may be on the journey, there are decisions to make about medical care, health plans, and the services and support that may be needed. Biogen is here to help patients learn about available options to decide which ones best fit their needs.

This guide provides information about health plan coverage for SPINRAZA, which is a prescription medicine approved by the **US Food and Drug Administration (FDA)** to treat SMA in children and adults. This guide also describes programs that are available to support your or your loved one's care.

Definitions for words that are **blue and bold** in this brochure can be clicked to navigate directly to the glossary. Additionally, all underlined page numbers listed throughout the guide can be clicked to navigate directly to that page number.

When navigating throughout the guide, please keep in mind the tabs on the right can direct you to that specific section.

THIS GUIDE EQUIPS YOU WITH TOOLS TO ADVOCATE FOR INSURANCE COVERAGE OF SPINRAZA TREATMENT FOR YOURSELF OR YOUR LOVED ONE

- Understand a health plan's coverage for SPINRAZA
- Learn about types of health plans
- Navigate a plan's approval process with the doctor and learn what to do if coverage for SPINRAZA is denied
- Understand options for financial assistance and connect with support services from SMA360°™

SMA360° services from Biogen are available only to those who have been prescribed SPINRAZA. SMA360° is intended for US residents only.

Individual results may vary based on several factors, including severity of disease, initiation of treatment, and duration of therapy.

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Before taking SPINRAZA, tell your healthcare provider if you are pregnant or plan to become pregnant.

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THE BIOGEN SMA360° TEAM WILL BE THERE THROUGHOUT THE SPINRAZA TREATMENT JOURNEY

FAMILY ACCESS MANAGER

Once the Biogen Start Form has been sent in by the doctor, a **Family Access Manager (FAM)** will reach out and can help

- Coordinate the logistics of starting treatment
- Prepare you or your loved one for the treatment journey by providing information on what to expect
- Connect with you or your loved one at the treatment center, to assist with logistics as necessary

Please remember that the doctor should be the primary resource for any questions related to SMA and SPINRAZA.

The relationship with your FAM should be comfortable for you and your family.

LEAD CASE MANAGER

Once enrolled in SMA360°, a **Lead Case Manager (LCM)** will call to follow up. LCMs can

- Help research health plan benefits and understand coverage
- Educate on the eligibility details of the Copay Program from Biogen,† which can potentially cover both the cost of your or your loved one's SPINRAZA prescription and the treatment procedure

SMA360™ Support services from Biogen

One program that can help you or your loved one with SPINRAZA treatment is SMA360°. Biogen created this support service especially for patients with SMA who are prescribed SPINRAZA. Please see page 36 for additional information.

*SMA360° services from Biogen are available only to those who have been prescribed SPINRAZA. SMA360° is intended for US residents only.

†Depending on income or, in some cases, if the medication is obtained from an out-of-network provider, there may be an annual cap that limits the amount of assistance that can be received over 1 year. Federal and state laws and other factors may prevent or otherwise restrict eligibility. Individuals receiving coverage from Medicare, Medicaid, the VA/DoD, TRICARE®, or any other governmental or pharmaceutical assistance may not be eligible. The Copay Program is only available once a claim has been submitted to and paid for by the insurance company. Individuals may remain enrolled in the Copay Program for as long as eligibility criteria are met. Contact an LCM for full eligibility requirements.

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CAMERON // AGE 2.5
INFANTILE-ONSET (TYPE 1)
SMA TREATED WITH SPINRAZA

NAVIGATING COVERAGE AND ACCESS TO SPINRAZA® (nusinersen)

Please see Important Safety Information on page 44 and accompanying full Prescribing Information.

UNDERSTANDING HOW SPINRAZA IS COVERED BY A HEALTH PLAN

A HEALTH PLAN'S MEDICAL POLICY

A medical policy is a set of guidelines a health plan uses to assess if a medical procedure or drug is **medically necessary** and eligible for coverage. A plan may set certain limits on coverage based on its medical policy, and may review and update their policies periodically.

What you can do

- ☑ Review and understand the health plan's medical policy before starting treatment with SPINRAZA. Request that the health plan send you its medical policy for SPINRAZA
- ☑ If you have or your loved one has a government health plan, such as **Medicaid** (see page 27) or **Medicare** (see page 30), ask your Family Access Manager (FAM) for more information about SPINRAZA coverage

HOW A HEALTH PLAN'S MEDICAL POLICY AFFECTS COVERAGE FOR SPINRAZA

The coverage under each medical policy for SPINRAZA can vary from plan to plan, and may require a **prior authorization (PA)** before SPINRAZA is covered (see page 10). Criteria for coverage may include age and type of SMA. Some patients may also face coverage restrictions because of treatment center and/or provider location.

In addition to the LCM through SMA360º, patients have a right to a case manager or patient advocate at the health plan if they would like one. Contact the health plan directly for more information.

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FREQUENTLY ASKED QUESTIONS

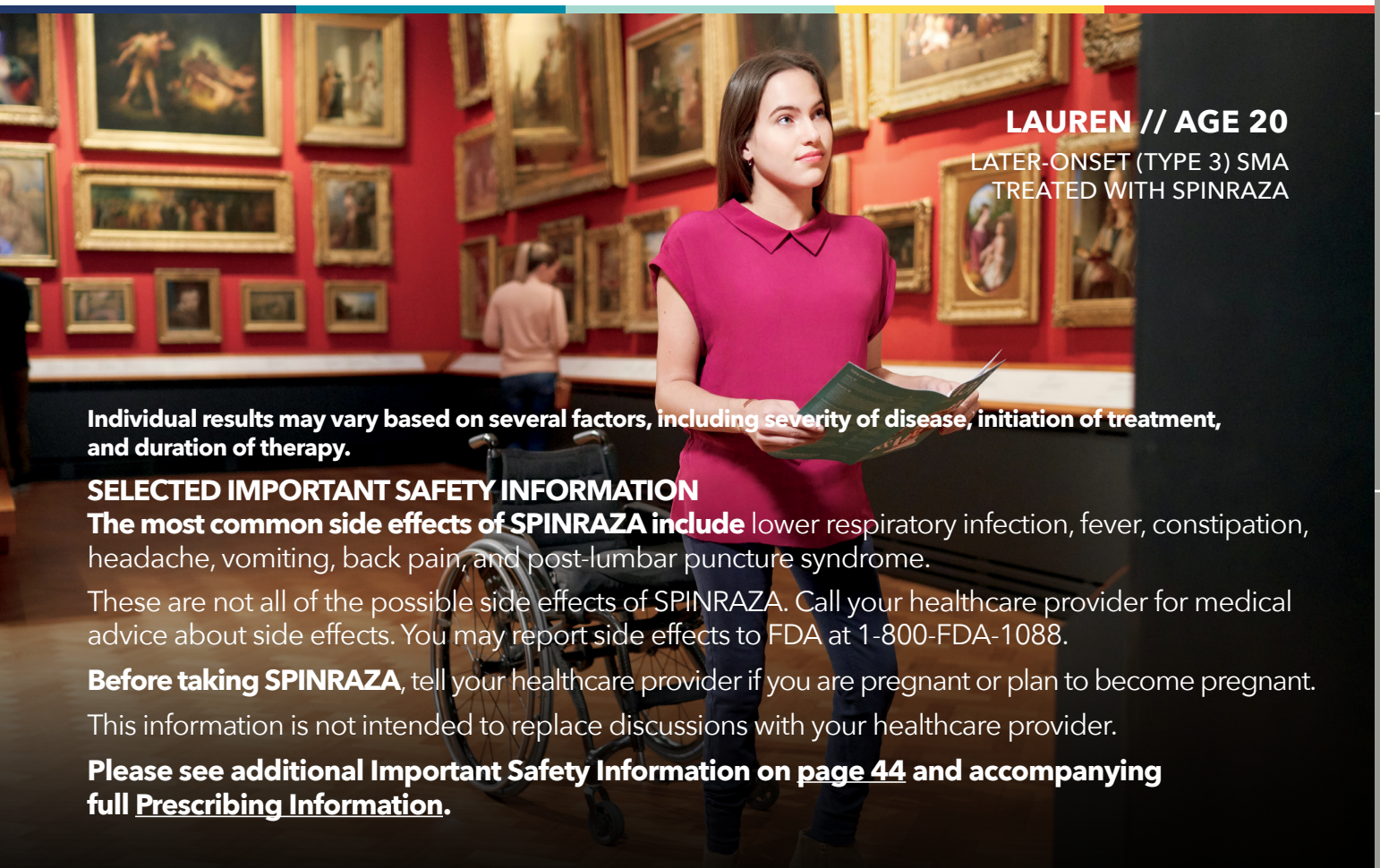
What can be done if the health plan does not cover SPINRAZA?

If you or a loved one with SMA does not meet your health plan's coverage, or there is no policy for SPINRAZA, there are steps that can be taken to get coverage.

Step 1: Contact the health plan and discuss treatment needs and coverage options. If insured through an employer, ask the employer's human resources department to advocate on the behalf of you or your loved one. By advocating, it shows the health plan that there are patients trying to get treatment.

Step 2: Encourage the doctor to call the health plan and request a **medical exception (ME)** (see page 11)

Step 3: Call your FAM for assistance. They can answer questions and provide guidance for finding support services and patient advocacy groups



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NAVIGATING A HEALTH PLAN'S APPROVAL PROCESS FOR SPINRAZA

THE HEALTH PLAN APPROVAL PROCESS FOR SPINRAZA

This diagram can help patients understand the steps to getting SPINRAZA approved and receiving treatment.

BENEFITS INVESTIGATION/ VERIFICATION

After receiving a prescription for SPINRAZA, the doctor's office will conduct a **benefits investigation/verification** (see page 9) to determine the health plan's benefit design, coverage requirements, and coding guidance for SPINRAZA.

REQUEST PA OR ME

Most insurers require a PA (see page 10) for SPINRAZA. The doctor's office will file the necessary paperwork.

This is the request for coverage approval from the health plan (**primary insurer** or **primary payer**) before treatment starts.

If SPINRAZA is not covered by the health plan, the doctor's office can request an ME (see page 11) and submit additional paperwork so that you may receive coverage.

IF PA OR ME DENIED, APPEAL DECISION

The health plan will review this information and will contact you and/or the doctor's office with a decision. Sometimes, even if treatment with SPINRAZA is medically necessary, coverage may be denied. If the health plan denies a PA or ME request, there is the option to **appeal** (see page 14).

RECEIVE TREATMENT

SPINRAZA is administered at a treatment center.

In order to keep receiving treatments, the doctor's office will submit requests for reauthorization (see page 13) on an ongoing basis.

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HOW LONG IS THE APPROVAL PROCESS?

There is no set timeline for the insurance approval process. There are several factors that can affect how long it takes for approval, such as

- The benefits investigation/verification
- Completing and submitting a Prior Authorization (PA) (see page 10)
- The internal review process at the health plan

If a patient has more than 1 plan, a benefits investigation/verification must be conducted with each, and required paperwork must be submitted. The time it takes to receive approval can vary from plan to plan. If the doctor feels that treatment is urgent, he or she may request an expedited review of the approval request (see page 16).

WHAT TO EXPECT

Benefits Investigation/Verification

Once a patient is prescribed SPINRAZA, the doctor's office will research the plan's coverage. This is called a benefits investigation/verification. The benefits investigation/verification helps the patient and the doctor's office understand

- Current coverage for SPINRAZA
- The steps and documents the insurer requires for approval such as a PA and a **Letter of Medical Necessity**
- Coverage restrictions, such as the need for a **referral** (**referral restriction**) or out-of-state/out-of-network restrictions
- If filing a request for an ME is necessary
- **Out-of-pocket costs**, including **deductibles**, **copayments**, and **coinsurance**

If the health plan does not cover SPINRAZA, an ME may be requested (see page 11).

What you can do

Learn what steps need to be taken for approval and what you can do to help. Be sure the doctor's office and FAM have all health plan and treatment information, including insurance cards. Missing or incomplete information can slow down the process.

SELECTED IMPORTANT SAFETY INFORMATION

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WHAT IS A PRIOR AUTHORIZATION?

A health plan may grant coverage for some services and drugs only after a PA is approved.

PAs are very common for drugs that treat rare diseases, such as SPINRAZA. A PA lets a health plan decide if the treatment is medically necessary. It also allows health plans to make sure that drugs are being used appropriately. Whether a patient is new to SMA treatment or has previously been on SPINRAZA or other SMA treatments, the same initial approval process will likely apply.

PA requirements vary among health plans. The doctor's office must complete and submit the PA form to the health plan along with any additional information requested. Documents and information commonly submitted with a PA for SPINRAZA include

- Health plan ID numbers for you or your loved one
- Test results confirming SMA diagnosis, such as genetic testing
- Baseline functional exam results and baseline labs
- Patient notes and medical history
- Medical articles about the disease and drug
- Letter of Medical Necessity, if needed
- Treatment center

What you can do

Ask the doctor's office if it has all the information it needs to submit the PA. If not, provide the information as soon as possible. FAMs can also help the doctor's office with the PA process.

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REQUESTING A MEDICAL EXCEPTION

Sometimes a treatment is not covered by a health plan. However, it may still be prescribed if the patient and their doctor's office request an ME.

ME requests require more specific documentation than PAs, such as a Letter of Medical Necessity from the doctor's office. Some states have laws that require health plans to respond to an ME request within a certain period of time. Contact your FAM to learn whether this applies in the state where you or your loved one live.

What you can do

Ask the doctor's office and FAM what steps need to be taken for approval of the ME. You may want to contact the health plan directly and advocate for yourself or for your loved one with SMA.

WHAT TO DO IF COVERAGE WAS DENIED

Sometimes, even if treatment with SPINRAZA is medically necessary, coverage may still be denied. If the health plan denies the PA or ME request, you can appeal. There may also be the option to request an independent **external review** (see page 14).

Speak with the health plan. You have the right to know why the request was denied. The plan will most likely provide in writing the reason for denial and how to appeal.

Coverage may be denied due to a billing, coding, or administrative error. If so, the doctor's office may also be able to resolve the issue without the necessity of a formal appeal. If this is the case, alert the FAM, who can follow up with the doctor's office.

WHAT HAPPENS WHEN A HEALTH PLAN APPROVES COVERAGE FOR SPINRAZA

1. The health plan will notify you, the doctor's office, and/or SMA360°.* Be sure to communicate any information received from the health plan with the doctor's office and FAM.

2. Once coverage is approved, follow up with the doctor's office to ensure an appointment is scheduled for your or your loved one's first treatment.

   You may also want to follow up with the health plan to understand coverage, clarify benefits for the drug and procedure, and ask about any out-of-pocket costs.

3. Confirm your or your loved one's appointment for treatment with your FAM. Frequent communication is important through this process.

4. SPINRAZA is shipped to the treatment location.

Because SPINRAZA is specialty drug, you may get a call from the **specialty pharmacy** to confirm the order. **It is very important to answer this call and speak to the specialty pharmacy**, or there may be a delay in scheduling treatment.

*SMA360° services from Biogen are available only to those who have been prescribed SPINRAZA. SMA360° is intended for US residents only.

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WHAT IS REAUTHORIZATION AND HOW OFTEN WILL IT HAPPEN?

Health plans typically approve SPINRAZA for a certain length of time or number of doses. But patients receiving SPINRAZA require ongoing therapy. This typically continues beyond the initial period approved by the health plan.

Health plans may require a PA renewal for SPINRAZA after a certain period. Reauthorization periods for SPINRAZA may vary among health plans, but

- They are usually 6 months to 1 year
- They typically cover 1 to 3 maintenance doses, depending on the timing of treatment and how it lines up with the reauthorization period

Health plans typically will reauthorize the use of SPINRAZA for patients who have a **clinical response**. The health plan's medical policy will define what it means to have a clinical response to treatment and it is important that patients document their SPINRAZA treatment response as well.

A response may include

- Improvement in a motor function
- No change in maintaining certain abilities
- Slowed disease progression

WHAT TO DO IF A REAUTHORIZATION REQUEST IS DENIED

There are many reasons that a reauthorization may be denied. Fortunately, there are several steps you and the doctor's office can take to try to reverse the health plan's decision, such as an appeal (see page 14).

What you can do

Use a symptom log to record your or your loved one's response to treatment.

- Responses can include maintaining self-care activities or gaining a new motor milestone function. Photos and videos may also help when sharing with the doctor
- This step is critical because the doctor's office may want to submit the symptom log to support the reauthorization request

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If a denial for SPINRAZA is received, time is critical for an appeal to be submitted. Contact the FAM and doctor's office right away for assistance.

REQUESTING AN APPEAL

Depending on the state where you or your loved one lives and the health plan, there are typically 3 levels for appeal. The doctor's office can write an appeal letter to the health plan or you can write an appeal letter of your own (see page 17).

LEVELS IN THE APPEALS PROCESS

Level 1: Internal Appeal/Request for Reconsideration

You or the doctor's office may contact the health plan and request that it reconsider its decision. The doctor may request to speak with the medical reviewer to resolve the issue.

Level 2: Internal Appeal/Medical Director

You or the doctor can request a second-level appeal. A medical director at the health plan who was not involved in the original decision usually reviews the second-level appeal.

Level 3: External Independent Review

If the denial cannot be resolved with the health plan, you may have the right to request an independent third-party review. This means the health plan will no longer have the final say regarding benefits and coverage. The health plan is required by law to accept the external reviewer's decision. Refer to the final denial letter sent by the health plan. This letter should tell you how the request must be made.

Your FAM may be able to help you get started with the appeal or discuss other options that may be available. Call your FAM directly or SMA360°* at 1-844-4SPINRAZA (1-844-477-4672), Monday through Friday, from 8:30 AM to 8 PM.

*SMA360° services from Biogen are available only to those who have been prescribed SPINRAZA. SMA360° is intended for US residents only.

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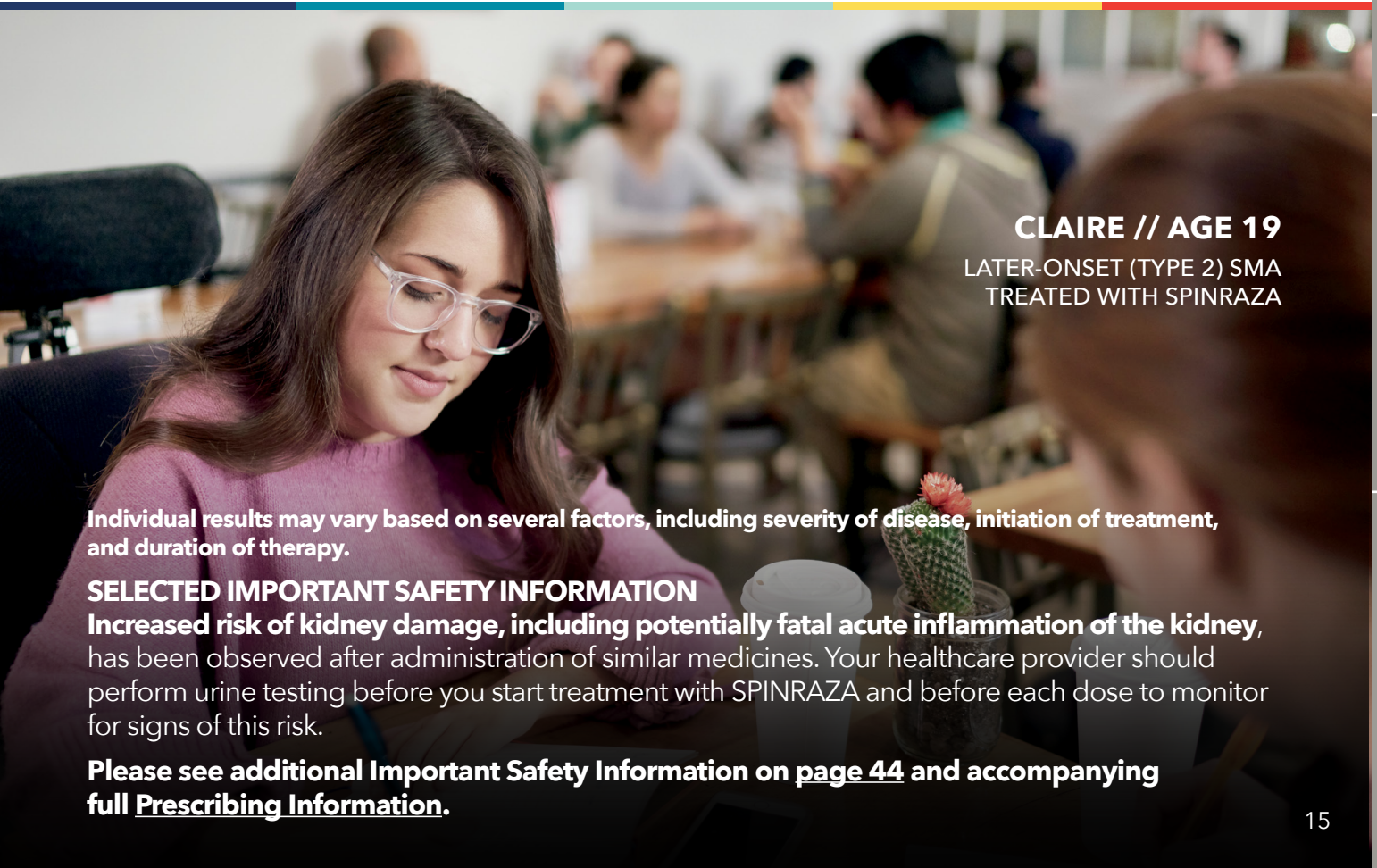
IF COVERAGE WAS DENIED BY A PRIMARY HEALTH PLAN AND THERE IS A SECONDARY HEALTH PLAN

A secondary health plan may be an option if the primary health plan denied coverage for SPINRAZA. You and the doctor's office can work together to advocate for coverage with the secondary plan.

What you can do

- ☑ Provide to the doctor's office the Explanation of Benefits (EOB) from the primary health plan about the SPINRAZA denial
- ☑ Call the secondary plan and explain the situation. Write down any information gathered during this call, as well as who you spoke with
- ☑ Tell the doctor's office or Biogen FAM any information that may help with the coverage request for the secondary plan



CLAIRE // AGE 19
LATER-ONSET (TYPE 2) SMA
TREATED WITH SPINRAZA

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REQUESTING AN APPEAL WHEN THE HEALTH SITUATION IS URGENT

In urgent situations, you may ask for an external review (see page 14) at the same time as an internal review. This may help speed up the process. You can file an expedited appeal if you are currently receiving treatment and the doctor believes a delay would be life threatening, affect the ability to regain maximum function, or subject you or your loved one to severe pain. The health plan must make a decision within 4 business days after the request is received.

WHERE TO FIND HELP WITH AN APPEAL

While working with the doctor's office, there are several additional places to get help with filing a request for an appeal:

State consumer assistance program

Some states have consumer assistance programs to help with appeals or requests for external review. The health plan's letter denying the request for coverage should have the contact information. You can also call the state insurance department for this information.

Patient advocate

You may request the help of a patient advocate to act on your behalf for a range of healthcare-related issues, including PAs and appeals. The Patient Advocate Foundation is a national nonprofit organization that helps patients settle issues with their insurers regarding access to care. Visit the Patient Advocate Foundation at **www.patientadvocate.org**.

An employer

If the health plan is administered by an employer, the employer may be able to help request an appeal. Contact the human resources department for more information.

SMA360™ Support services from Biogen

FAMs and SMA360° do not file appeals with health plans, but FAMs may be able to help you get started with an appeal. Call the FAM directly or SMA360° at **1-844-4SPINRAZA (1-844-477-4672)**, Monday through Friday, from 8:30 AM to 8 PM.

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SUGGESTIONS FOR WRITING A LETTER OF APPEAL

As mentioned earlier, you may also choose to write and submit a letter of appeal to the health plan as a way to potentially reverse the denial of coverage. A letter from the patient or caregiver can have a meaningful impact with a health plan.

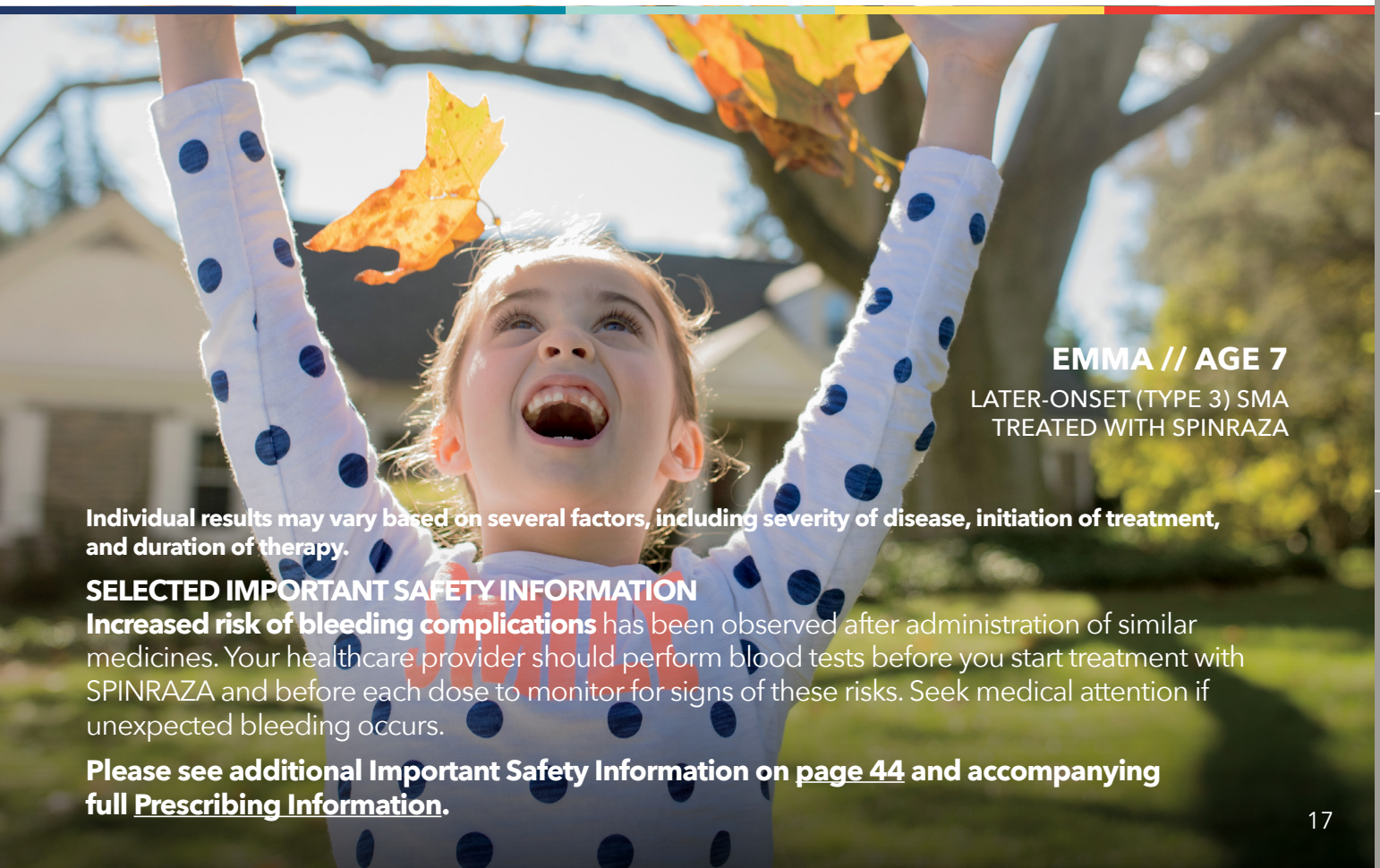
The outline on the next page can help you write and submit a letter to show the health plan why treatment with SPINRAZA should be covered.

WHEN AND HOW SHOULD A LETTER OF APPEAL BE SUBMITTED?

The letter can be submitted to the health plan at any time during the appeals process, but it is suggested to submit it before an external review is done (see page 14).

Once the letter is written, it should be sent to the health plan. Check the denial letter to find out to whom the letter should be sent, and for any relevant deadlines.

A copy of the letter should also be provided to the prescriber so that he or she is aware of any communication with the plan. The prescriber may also choose to make the letter a part of his or her appeal.



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SAMPLE OUTLINE: SUGGESTIONS FOR WRITING A LETTER OF APPEAL

Begin with an explanation

Let the plan know that this letter is being written to appeal the denial of coverage for SPINRAZA and ask the plan to reconsider this decision.

Provide a brief background of the patient

If you are not the patient, explain your relationship to the patient (eg, caregiver, father, mother, etc). You may also wish to include the following

- A description of yourself or your loved one, your family, and any family history of SMA
- An overview of your or your loved one's education and employment (if applicable)
- A photo of you or your loved one (optional)

Describe your or your loved one's SMA

Let the health plan know

- Age at which symptoms first appeared and symptoms that were later found to be related to SMA but were not recorded (such as falling, walking too late, trouble feeding)
- Genetic confirmation of the diagnosis
- Treatment history, including details of any previous SPINRAZA treatment and/or other SMA treatments
- How your SMA has worsened over time (give specific examples and time frames)

Describe how SMA has affected your or your loved one's activities and daily tasks

Here are some examples, but there may be others.

- Bathing
- Dressing
- Grooming
- Using the restroom independently
- Walking
- Shopping
- Cooking
- Eating and drinking
- Doing housework
- Attendance in school or school activities
- Ability to work or hold a job
- Driving or using public transportation

Give examples of how SMA has required you or your loved one to adapt

Include relevant information about

- How caregivers and/or support people may be necessary for you or your loved one
- Your or your loved one's use of mobility devices, such as walkers or wheelchairs

Describe what you believe SPINRAZA has done, or could do, for you or your loved one

Give as much detail as possible. Describe

- How SPINRAZA has helped, or could help, you or your loved one
- Why SPINRAZA has been, or would be, important to you or your loved one
- Specific examples of the impact the drug has made (if applicable)

Conclude the letter

End the letter by

- Summarizing the main points
- Restating the request for the plan to reconsider its decision to deny coverage
- Including your contact information

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QUESTIONS TO ASK A HEALTH PLAN

This section may help you start a conversation with the health plan about benefits for SPINRAZA. Use the questions below to gather specific information from the health plan.

SPINRAZA coverage questions

- Representative name and ID number
- What does the plan cover for treatment with SPINRAZA? What does it not cover?
- Will the plan cover a hospital stay or ancillary service, such as anesthesia, if needed?
- Is a referral or prior authorization needed for treatment with SPINRAZA?
- What will the doctor need to provide in order to receive approval for SPINRAZA?
- Does SPINRAZA need to be reauthorized after initial approval? When? How often?
- What benefit exclusions apply to treatment with SPINRAZA?
- What restrictions are in place before a patient can get SPINRAZA?
- What documentation needs to be provided?
- What will be the out-of-pocket costs to pay for SPINRAZA? Deductibles? Copays? Out-of-pocket maximum?
- What will be the out-of-pocket costs to pay for SPINRAZA administration? Deductibles? Copays? Out-of-pocket maximum?
- The plan is for treatment with SPINRAZA to be received at [name of SMA treatment center/ name of facility]. Is this treatment center covered by the plan?
- If treatment with SPINRAZA needs to be provided out of network and/or out of state. Is it covered? What is the exception process?
- If SPINRAZA is not covered for me or my loved one, what is considered medically necessary for treatment with SPINRAZA? What supporting documents are required?
- If coverage is denied, what is your appeals process?

Health plan questions

- What types of plans are offered?
- What is the monthly premium?
- What are the copays for doctor visit (general and specialist)?
- What is the coverage for a hospital stay?
- What is the pharmacy or prescription benefit coverage?
- Are there any limitations on which physicians can be visited?

Therapy and service questions

- Is physical therapy covered? If yes, under which plans is it covered?
- Is respiratory therapy covered? If yes, under which plans is it covered?
- Is the medical equipment needed by me or my loved one covered by the plan?
- Is there a copayment?

Medigap questions

- What does this Medigap plan cover?
- How much will it cost each month?
- Do you charge the same premium as other insurance companies for the same policy?
- When does coverage begin?

SELECTED IMPORTANT SAFETY INFORMATION

Increased risk of bleeding complications has been observed after administration of similar medicines. Your healthcare provider should perform blood tests before you start treatment with SPINRAZA and before each dose to monitor for signs of these risks. Seek medical attention if unexpected bleeding occurs.

Please see additional Important Safety Information on page 44 and accompanying full Prescribing Information.

UNDERSTANDING HEALTH PLANS

Please see Important Safety Information on page 44 and accompanying full Prescribing Information.

WHAT TO CONSIDER WHEN CHOOSING A HEALTH PLAN

WHAT A HEALTH PLAN COVERS

Typically, health plans cover general categories of healthcare services. These include doctor visits, medical tests, and treatments. Each plan may have different rules about how spinal muscular atrophy (SMA) care is covered. Talk to your health plan about specifics.

WHAT DOCTORS, TREATMENT CENTERS, AND PHARMACIES ARE IN THE PLAN

The health plan is likely to have a network of providers who have agreed to provide services to its members. The out-of-pocket cost for seeing an **in-network provider** is typically lower than **out-of-network providers**. In some cases, if you or your loved one choose to see an out-of-network provider, you may be responsible for 100% of the provider's bill. This depends on the type of coverage and the specifics of the plan.

People with Medicaid (see page 27) are often limited to seeing participating providers in their state. Contact the state Medicaid office for more information.

People with SMA may have to travel long distances and/or out of state to access treatment centers that specialize in SMA. This means that these people will receive care from out-of-state or out-of-network providers. Generally, states must pay for the out-of-state services to the same extent that an in-state service would be paid if

- It is an emergency
- The state decides that the needed services are more easily available in another state
- The health of the patient would be endangered if they needed to travel back to their home state
- People in the area often use an out-of-state provider—for example, in areas that border another state

WHAT YOU OR YOUR LOVED ONE MAY PAY

Health plans take on a portion of the cost of medical care and medicines, but they don't take on all of the costs. Often the patient must pay some of the cost. This is called **cost sharing**.

Examples of cost sharing include deductibles, coinsurance, and copayments. Some preventive services that patients get with in-network providers do not require cost sharing. In addition, people who have Medicaid often pay a lower cost-sharing amount.

SELECTED IMPORTANT SAFETY INFORMATION

Increased risk of kidney damage, including potentially fatal acute inflammation of the kidney, has been observed after administration of similar medicines. Your healthcare provider should perform urine testing before you start treatment with SPINRAZA and before each dose to monitor for signs of this risk.

Please see additional Important Safety Information on page 44 and accompanying full Prescribing Information.

HEALTH PLAN OPTIONS

There are many different types of health plan options that may help cover some or most of the cost of SPINRAZA treatment. They may provide different levels of coverage and operate in different ways.

There are 2 main types of health insurance available in the United States:

Commercial health insurance (see page 24) includes private insurance plans provided by employers and unions. Commercial health plan coverage may also be purchased through firms or the **insurance exchange** (see page 25).

Government-funded health insurance includes coverage offered through programs funded by the state or federal government, such as Medicare (see page 30), Medicaid (see page 27), Children's Health Insurance Program (CHIP) (see page 28), TRICARE®, and Veterans Administration Care.

This section provides you an overview of the different types of health insurance.

You or your loved one may be able to get 1 or more of these plans to help cover the cost of SPINRAZA. Most individuals with SMA have more than 1 health plan.

WHAT IS OPEN ENROLLMENT?

Open enrollment is a period of time when changes can be made to one's health or drug plan for the next year. Open enrollment is a great opportunity for patients to review their plan benefits and evaluate whether current coverage is meeting their needs or if out-of-pocket expenses could be lowered. Patients can keep their current plan or compare plans to find one with better coverage.

If the patient has a **Medicare Advantage** or **Medicare** plan, they may make changes for the coming year between October 15 and December 7. If the patient has a commercial health plan, open enrollment usually begins late in the calendar year and continues for several weeks. Check with your or your loved one's plan, employer, or benefit manager for the actual dates of open enrollment. Coverage will begin on January 1 of the next year if a plan change was made.

SELECTED IMPORTANT SAFETY INFORMATION

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These are not all of the possible side effects of SPINRAZA. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Before taking SPINRAZA, tell your healthcare provider if you are pregnant or plan to become pregnant.

This information is not intended to replace discussions with your healthcare provider.

Please see additional Important Safety Information on page 44 and accompanying full Prescribing Information.

WHAT ARE THE DIFFERENT TYPES OF COMMERCIAL HEALTH PLANS?

There are many types of commercial health plans. Each type of plan provides varying levels of coverage and operates in a unique way.

How each type of commercial health plan works

Type of health plan	Has a network of providers?	Need a referral to see a specialist?	What happens if I need out-of-network care?
Health Maintenance Organization (HMO)	**Yes**	**Yes**	HMOs cover out-of-network care if • The HMO's **network** of doctors does not have the experience to treat a certain health problem • A network doctor refers patients to an out-of-network doctor • There is an emergency
Exclusive Provider Organization (EPO)	**Yes**	**No**	EPOs do not cover out-of-network care, even when the plan's doctors do not have the experience to treat a certain health problem. EPOs must pay for out-of-network care if there is an emergency
Preferred Provider Organization (PPO)	**Yes**	**No**	PPOs provide out-of-network care but may not pay for the full cost of treatment. If patients choose to see an out-of-network doctor, they may have to pay for some of their treatment, even if it is an emergency
Point-of-Service (POS) Plan	**Yes**	**No**	POS plans provide out-of-network care but patients may have higher costs for out-of-network providers
Indemnity or **Fee-for-Service (FFS)**	**No**	**No**	Not applicable because FFS plans do not have a **provider network**. Patients may visit any provider or hospital but may have to pay a higher share of the cost

SELECTED IMPORTANT SAFETY INFORMATION

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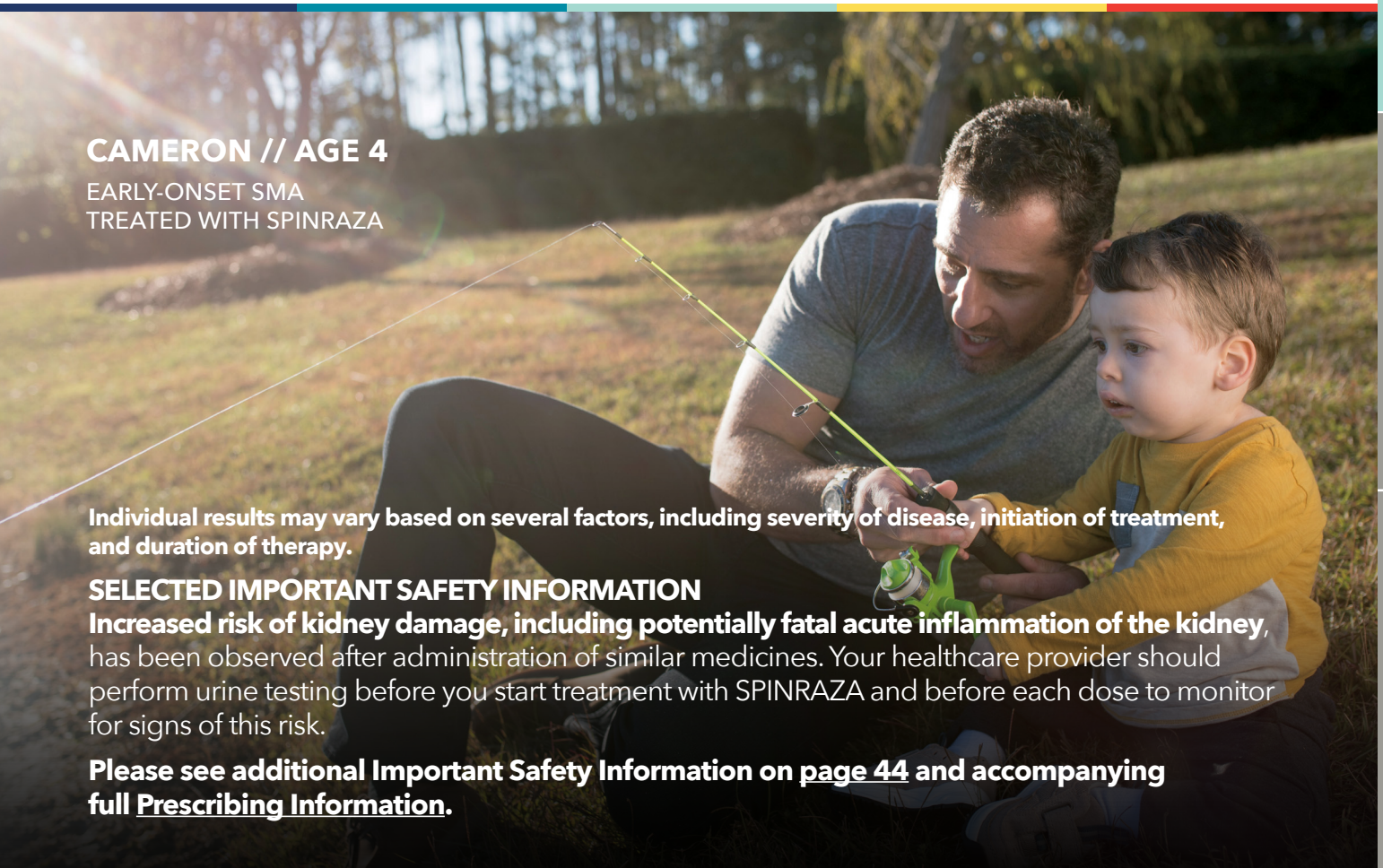
High-deductible health plan

This type of benefit usually has a lower monthly **premium** than traditional benefits. But patients will have to pay more money out-of-pocket before the plan will pay for any expenses. There are ways to help pay for the expenses in a **high-deductible health plan**, including a health savings account (HSA), health reimbursement account (HRA), or flexible spending account (FSA). The money in these tax-free accounts can be used to pay for some medical expenses.

Health insurance marketplace

The health insurance marketplace, also known as *exchange*, helps people buy health plans when they cannot get them another way like through an employer. For more information about what the marketplace offers, visit **www.healthcare.gov**.

Commercial health plans can offer different coverage. They each have different rules and costs. Call the health plan to learn more about the services it covers, including the coverage for SPINRAZA. The number to call is typically located on the back of the health plan card. Please also refer to the "Questions to Ask A Health Plan" (see page 20).



Individual results may vary based on several factors, including severity of disease, initiation of treatment, and duration of therapy.

SELECTED IMPORTANT SAFETY INFORMATION

Increased risk of kidney damage, including potentially fatal acute inflammation of the kidney, has been observed after administration of similar medicines. Your healthcare provider should perform urine testing before you start treatment with SPINRAZA and before each dose to monitor for signs of this risk.

Please see additional Important Safety Information on page 44 and accompanying full Prescribing Information.

WHAT ARE THE TYPES OF GOVERNMENT-FUNDED HEALTH PLANS?

Many people get health plans through a program that is funded by the state or federal government. These programs include

Medicaid

CHIP

Medicare

US Department of Defense (DoD)/ TRICARE®

US Department of Veterans Affairs (VA)

If a child has SMA, Medicaid (see page 27) or CHIP (see page 28) are the programs that will most likely help pay for the cost of the child's care, even if they have a commercial plan.

Medicare (see page 30) is an insurance option for adults with SMA who receive disability benefits from Social Security. TRICARE and the VA provide health coverage for US military service members, veterans, and their families. TRICARE may cover the cost of treatment for a child with SMA if a parent has TRICARE coverage for the family. Medicare can also be supplemented with Medicaid to provide additional coverage.

SELECTED IMPORTANT SAFETY INFORMATION

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These are not all of the possible side effects of SPINRAZA. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Before taking SPINRAZA, tell your healthcare provider if you are pregnant or plan to become pregnant.

This information is not intended to replace discussions with your healthcare provider.

Please see additional Important Safety Information on page 44 and accompanying full Prescribing Information.

HOW MEDICAID WORKS FOR PEOPLE WITH SMA

Medicaid provides low-cost or free health coverage to millions of Americans, including people with low income, people with disabilities, and pregnant women.

Medicaid can help patients afford medical costs for SMA and other conditions by covering

- Hospital and doctor or nurse visits
- X-rays
- Home healthcare
- Medical tests
- Transportation to medical care

Medicaid is run by each state. Each state has different requirements for income, the number of people in the household, family status, and other factors. The state may also help pay for other care for SMA, such as medicines, occupational therapy, case management, breathing care, medical equipment/procedures, and physical therapy.

SUPPLEMENTING A COMMERCIAL HEALTH PLAN WITH MEDICAID

People with SMA may have a commercial health plan at the time of diagnosis. Many may also sign up for Medicaid to help pay for costs that their commercial health plan does not cover.

For patients with SMA, the first step to getting Medicaid is applying for Social Security Supplemental Security Income (SSI) benefits from Social Security (see page 28).

Need help applying for Medicaid?

You can contact the state Medicaid office to learn about how to apply for Medicaid. To get the phone number for the state office, visit **www.medicaid.gov** or call **1-877-267-2323** and follow the prompts.

SELECTED IMPORTANT SAFETY INFORMATION

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Please see additional Important Safety Information on page 44 and accompanying full Prescribing Information.

OTHER GOVERNMENT ASSISTANCE SERVICES

SUPPLEMENTAL SECURITY INCOME

SSI is a federal program that provides monthly payments to help adults and children with disabilities who have limited income. SMA is a condition that fits the definition of disability to qualify for SSI for both adults and children. SSI will look at a portion of the income (money you receive) and resources (things you own) that you and your spouse have to see if you or your loved one qualify.

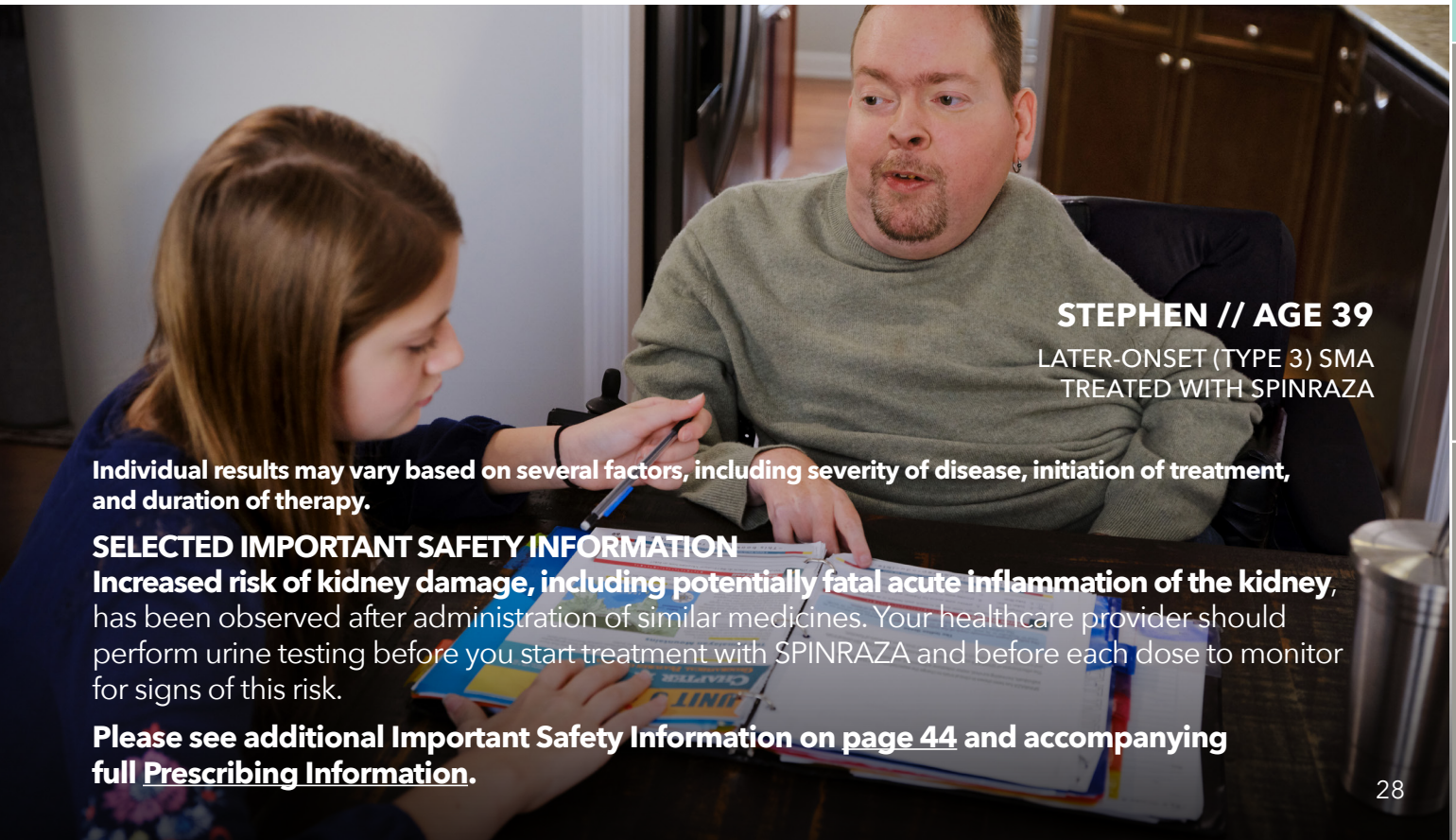
Signing up for SSI will help you or your loved one become enrolled in Medicaid and other programs. To learn more about SSI, visit **www.socialsecurity.gov** or call **1-800-772-1213**.

CHILDREN'S HEALTH INSURANCE PROGRAM

CHIP provides low-cost insurance that covers a wide range of benefits for children in families with incomes above the level that qualifies for Medicaid but who cannot afford to buy private health insurance. Children with SMA who are younger than 19 years may be eligible for CHIP.

You can apply for CHIP directly with your state Medicaid or CHIP agency.

Not all doctors accept patients who have Medicaid or CHIP. Be sure to ask the office staff at the treatment center if Medicaid or CHIP is accepted when an appointment is made.



STEPHEN // AGE 39
LATER-ONSET (TYPE 3) SMA
TREATED WITH SPINRAZA

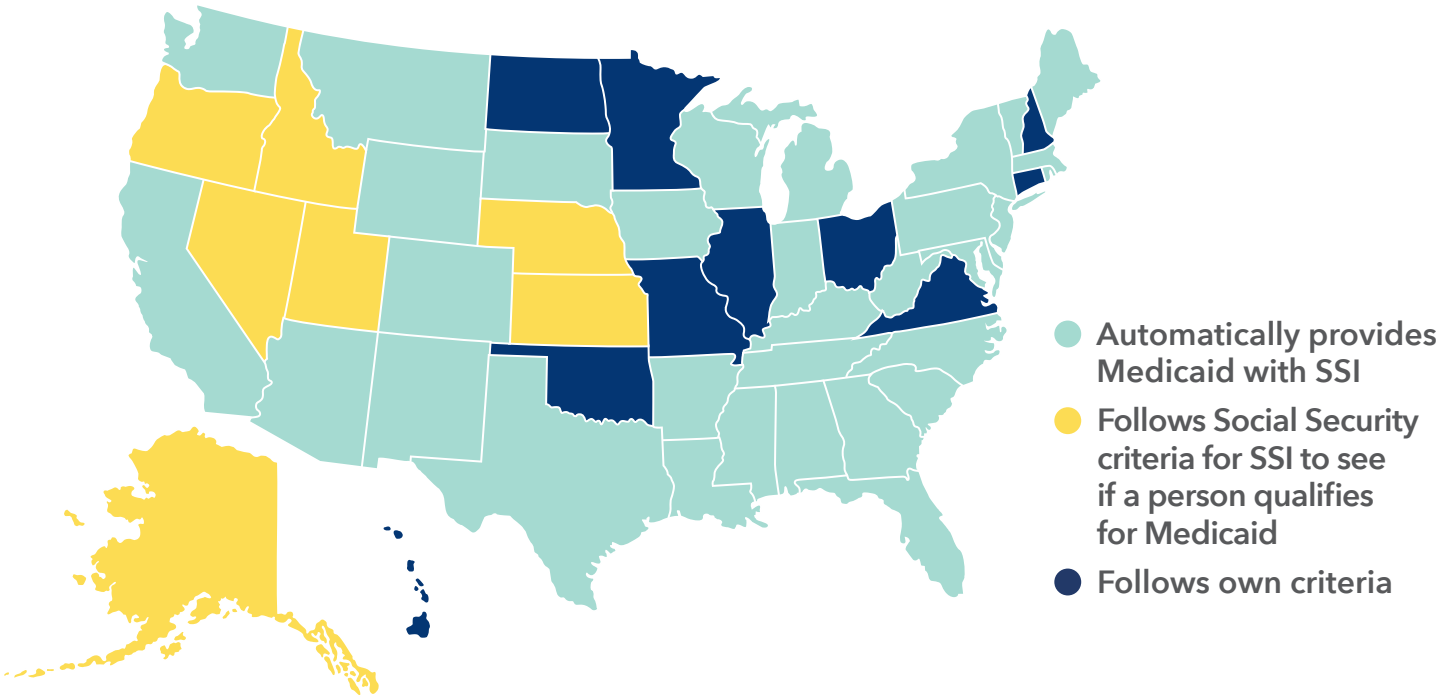
Individual results may vary based on several factors, including severity of disease, initiation of treatment, and duration of therapy.

SELECTED IMPORTANT SAFETY INFORMATION
Increased risk of kidney damage, including potentially fatal acute inflammation of the kidney, has been observed after administration of similar medicines. Your healthcare provider should perform urine testing before you start treatment with SPINRAZA and before each dose to monitor for signs of this risk.

Please see additional Important Safety Information on page 44 and accompanying full Prescribing Information.

STATE MEDICAID ELIGIBILITY AND ENROLLMENT POLICIES

There are 3 types of Medicaid enrollment policies. See the map for how Medicaid enrollment is determined in your or your loved one's state.



In most states, a person with SMA who qualifies for SSI benefits is automatically enrolled in Medicaid. Contact your state Medicaid office for more information about the eligibility guidelines.

MEDICAID WAIVER PROGRAMS

People living with SMA may qualify for other Medicaid assistance not based solely on income. This can be done through Medicaid waivers, which is when a state Medicaid service waives the rules so that someone can be eligible for Medicaid.

To learn more about waivers available, visit **medicaid.gov**. **Kidswaivers.org** is another helpful resource to learn more about available Medicaid waivers for children.

SELECTED IMPORTANT SAFETY INFORMATION

The most common side effects of SPINRAZA include lower respiratory infection, fever, constipation, headache, vomiting, back pain, and post-lumbar puncture syndrome.

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Before taking SPINRAZA, tell your healthcare provider if you are pregnant or plan to become pregnant.

This information is not intended to replace discussions with your healthcare provider.

Please see additional Important Safety Information on page 44 and accompanying full Prescribing Information.

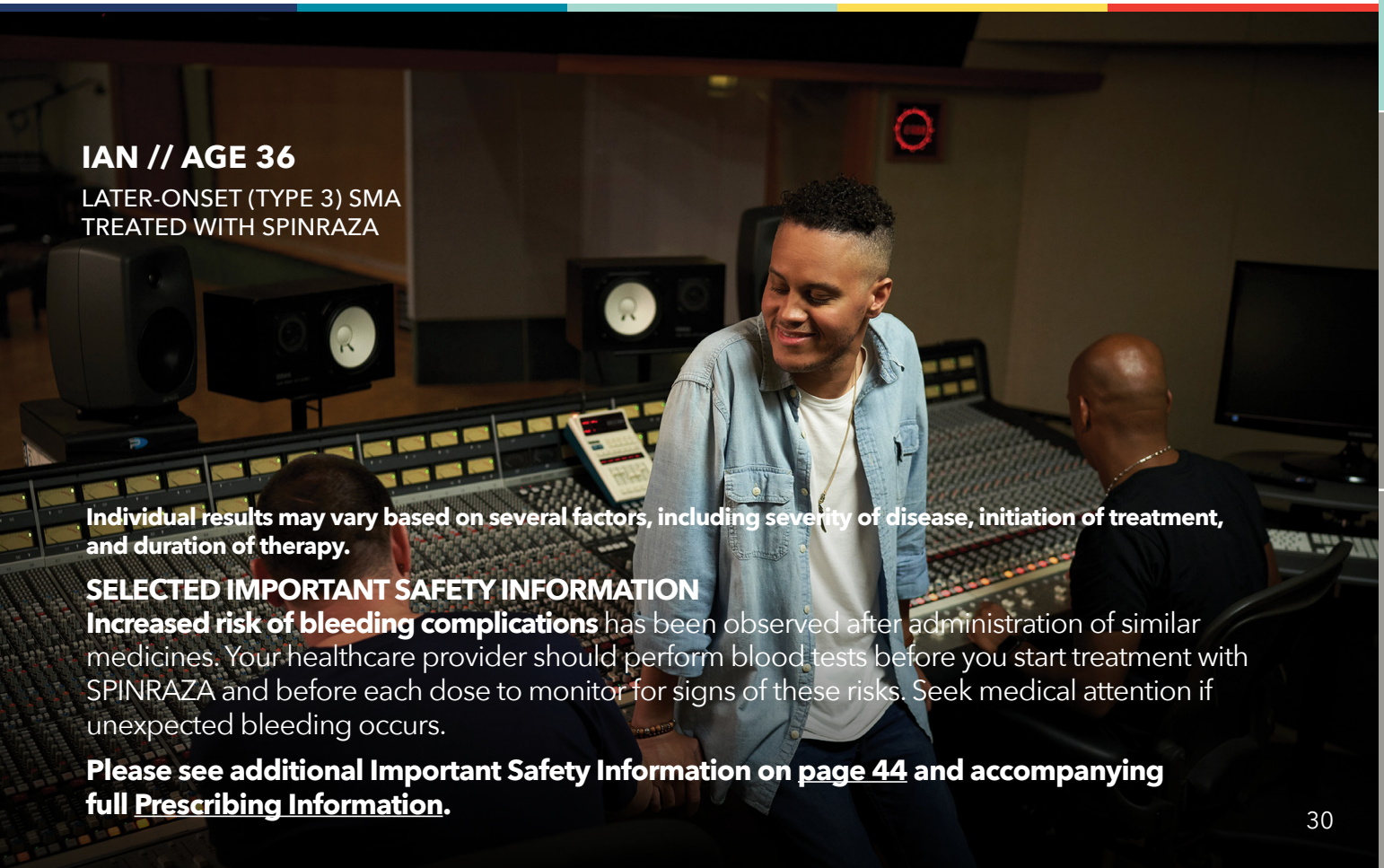
HOW MEDICARE WORKS FOR PEOPLE WITH SMA

MEDICARE ELIGIBILITY FOR PEOPLE WITH SMA

Medicare is a health plan offered by the government. It covers

- People aged 65 years and older
- People younger than age 65 years with certain disabilities, such as SMA
- People diagnosed with end-stage renal (kidney) disease

Medicare covers about 1 in 4 adults with SMA (aged 18 years and older).



IAN // AGE 36

LATER-ONSET (TYPE 3) SMA
TREATED WITH SPINRAZA

Individual results may vary based on several factors, including severity of disease, initiation of treatment, and duration of therapy.

SELECTED IMPORTANT SAFETY INFORMATION

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HOW DOES MEDICARE WORK?

Medicare has 4 parts to help cover services:

PART A

Part A is hospital insurance. Part A covers care in a hospital, nursing home care, hospice care, and home healthcare. **Part A covers SPINRAZA** when it is received as an inpatient during a hospital stay.

PART B

Part B is medical insurance. Part B covers outpatient care (doctor's office visits and visits to treatment centers for injections, such as SPINRAZA), some home healthcare services, medical equipment, wellness services, lab tests, and select preventive screenings. **Part B covers SPINRAZA** when it is received from the doctor as an outpatient, for instance, at an SMA treatment center.

Parts A and B are known as "Original Medicare"

PART C

Part C is also called Medicare Advantage (MA). Part C or MA plans are sold by private insurance companies approved by Medicare. These plans include all services covered under Part A and Part B, with many offering prescription drug coverage. Part C may offer additional benefits as well.

For more information about MA plans in your area, visit the **MA website**.

PART D

Part D is prescription drug coverage. Part D covers drug costs (pills that are swallowed, injections patients give themselves, inhaled treatments). Part D plans are sold by private insurance companies approved by Medicare. These plans do not cover SPINRAZA, but they cover other drugs you or your loved one may need.

SELECTED IMPORTANT SAFETY INFORMATION

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PATHS TO MEDICARE COVERAGE FOR PEOPLE WITH SMA

The most likely path to Medicare for patients with SMA is to be declared disabled before the age of 65 years. These patients must first apply for and receive Social Security Disability Insurance (SSDI) benefits. To qualify for SSDI benefits, patients must have a past work history and can no longer work due to disability.

Once patients receive SSDI for 24 months, they will automatically be enrolled in Original Medicare (Parts A and B) (see page 31).

HOW TO GET A DECISION SOONER WHEN APPLYING FOR SSDI BENEFITS

People with SMA can speed up the decision process for SSDI benefits by applying for the Social Security Administration's **Compassionate Allowances**. SMA is a condition that fits the definition of a disability to qualify for SSDI and compassionate allowances.

You can apply for SSDI benefits online at www.ssa.gov or by calling 1-800-772-1213. Learn how to sign up for Medicare by visiting **www.medicare.gov**.

SELECTED IMPORTANT SAFETY INFORMATION

The most common side effects of SPINRAZA include lower respiratory infection, fever, constipation, headache, vomiting, back pain, and post-lumbar puncture syndrome.

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Before taking SPINRAZA, tell your healthcare provider if you are pregnant or plan to become pregnant.

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GETTING HELP TO PAY OUT-OF-POCKET COSTS FOR ORIGINAL MEDICARE

Medicare Supplement Insurance policies, also known as Medigap plans, can help pay some of the costs that Original Medicare does not. This includes copayments, coinsurance, and deductibles. Medigap policies are sold by private insurance companies. They must follow federal and state laws. Medigap policies are not available to people covered by a Medicare Advantage plan (Part C). Patients must have Medicare Part A and Part B to have a Medigap policy (see page 31).

There are up to 10 types of Medigap plans. Most will cover the full cost of the coinsurance for SPINRAZA under Medicare Part B.

Call **1-800-MEDICARE (1-800-633-4227)** or go to **www.medicare.gov** to find Medigap policies in your area or for more information.

Did you know? If patients have original Medicare, out-of-pocket costs are capped in the hospital outpatient setting. This means that for some patients, out-of-pocket costs may be limited to the Medicare Part A deductible. Contact Medicare to find out if this applies to you or your loved one.

HOW MEDICARE WORKS WITH OTHER INSURANCE PLANS

Some people with Medicare may also have another health plan. When there is more than 1 health plan, a coordination of benefits rule decides which plan pays first. It is important that both plans agree to the coordination. The health plan that pays first is the primary payer or primary insurer. This plan pays up to the limits of its coverage. The plan that pays the cost not covered by the primary payer is the **secondary payer** or **secondary insurer**.

Individuals with SMA typically have at least 2 health plans to cover medical and drug costs.

SELECTED IMPORTANT SAFETY INFORMATION

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CONTINUING SPINRAZA TREATMENT WHEN INSURANCE CHANGES

It is important to track and understand health insurance changes if they occur. For example, there may come a time when a patient moves from Medicaid (see page 27) to Medicare (see page 30), or when an insurance change is required because of a patient's age. In that case, Medicare becomes the primary insurance plan, and Medicaid the secondary insurer.

- Some health plans require a new authorization for treatment. If your or your loved one's insurance changes, you will need to find out if a new authorization is required
- If the primary insurance plan changes and the provider submits a claim to the wrong primary plan, it will likely be rejected and the claim will need to be resubmitted to the right insurer. This can cause a significant delay in continuing treatment

WHEN MEDICARE AND MEDICAID WORK TOGETHER

Medicaid can also help fill the gap in Medicare coverage for people with SMA and low incomes. People who are eligible for both Medicare and Medicaid are known as "**dual eligibles**."

- If a patient qualifies for both, Medicare is the primary payer. Medicaid then pays for all other eligible costs not covered by Medicare
- If a patient qualifies for Medicare but not Medicaid, a Medicare Savings Program may be available. These programs are administered through state Medicaid offices. They may help pay for some of the costs that Medicare does not cover

Even if you think you or your loved one may not qualify for a Medicare Savings Program, it is important to apply. Contact the state Medicaid office for more information. The telephone number can be found at **www.medicare.gov/contacts** or by calling **1-800-MEDICARE (1-800-633-4227)**.

FINANCIAL ASSISTANCE AND BIOGEN RESOURCES

Please see Important Safety Information on page 44 and accompanying full Prescribing Information.

FINANCIAL ASSISTANCE AND BIOGEN RESOURCES

NAVIGATING THE COST OF TREATMENT

Today's ever-changing insurance landscape can be overwhelming. SMA360°* insurance and financial assistance programs are designed to help you understand insurance benefits for SPINRAZA and find the most affordable way to start and stay on treatment as prescribed by the doctor.

SMA360° Support services from Biogen

ENROLLING IN SMA360°

The HCP can help with enrollment in SMA360° once a decision is made to start SPINRAZA. Provide patient information on the SPINRAZA Start Form, and the doctor will complete the form's medical section. The form will then be submitted to enroll you or your loved one in the SMA360° program. For more information about SMA360° services, contact an LCM at **1-844-4SPINRAZA (1-844-477-4672)**, Monday through Friday, from 8:30 AM to 8 PM ET.

To help make informed decisions, a Family Access Manager (FAM) and Lead Case Manager (LCM) from SMA360° can

- Review insurance benefits to help you understand current coverage
- Communicate with doctors working on your or your loved one's behalf to obtain prior authorization (PA) for treatment (see page 10)
- Provide support in the event of an insurance denial (see page 11)
- Educate you about eligibility for the Copay Programs from Biogen† (see page 37)
- Supply background and resources to refer you to third-party charity organizations
- Counsel you about adding or changing insurance coverage

*SMA360° services from Biogen are available only to those who have been prescribed SPINRAZA. SMA360° is intended for US residents only.

†Depending on income or, in some cases, if the medication is obtained from an out-of-network provider, there may be an annual cap that limits the amount of assistance that can be received over 1 year. Federal and state laws and other factors may prevent or otherwise restrict eligibility. Individuals receiving coverage from Medicare, Medicaid, the VA/DoD, TRICARE, or any other governmental or pharmaceutical assistance may not be eligible. The Copay Program is only available once a claim has been submitted to and paid for by the insurance company. Individuals may remain enrolled in the Copay Program for as long as eligibility criteria are met. Contact an LCM for full eligibility requirements.

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Before taking SPINRAZA, tell your healthcare provider if you are pregnant or plan to become pregnant.

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Please see additional Important Safety Information on page 44 and accompanying full Prescribing Information.

FINANCIAL ASSISTANCE PROGRAMS

Biogen offers 2 Copay Programs for eligible patients receiving SPINRAZA. Please note that these are 2 different programs that must be enrolled in separately as needed.

Drug Copay Program

- Generally, all individuals on nongovernment insurance are eligible, regardless of income, and there is no annual maximum on the amount Biogen will cover as part of the program. Insurance will be billed first and must pay before copay assistance will be applicable
- Individuals receiving coverage from Medicare, Medicaid, the VA/DoD, TRICARE®, or any other governmental or pharmaceutical assistance may not be eligible

Procedure Copay Program

- In addition to the above criteria, patients are eligible for this program if they meet the following requirements:
  - They are not a resident of Massachusetts, Michigan, Minnesota, or Rhode Island
  - The doctor submits a request for treatment using an approved procedure code for anesthesia, imaging procedures, and/or surgical procedure/drug administration. Please note that only codes approved by Biogen are eligible under the program

Note: The Procedure Copay Program covers specific, approved services directly related to the injection of SPINRAZA.

What to do if you or your loved one get an unexpected bill

Even if a patient is enrolled in one of these copay programs, there may be times when they receive an unexpected bill from the doctor's office. Determine where the bill is coming from and refer to the Explanation of Benefits (EOB) you or your loved one received from the health plan. Contact the FAM or LCM for help navigating challenges with unexpected medical bills.

Third-party funding assistance

If it is determined that a patient is not eligible for the Copay Program, SMA360° can help find charitable organizations that may provide third-party assistance.

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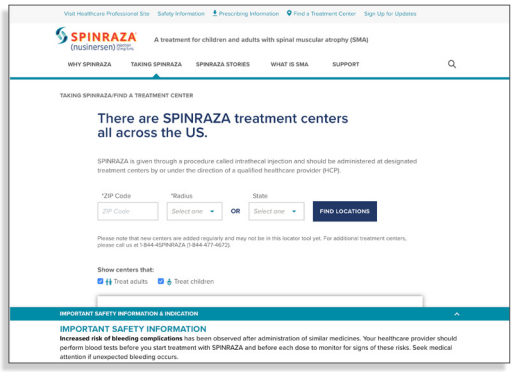
ADDITIONAL BIOGEN RESOURCES

FINDING A SPINRAZA TREATMENT CENTER

At **SPINRAZA.com**, you can use an interactive tool that makes it easy to find a treatment center in the area that administers SPINRAZA. Search by zip code to see a map of facilities that are close, along with addresses, direct contact information, and doctors who administer SPINRAZA at each location. The tool also allows sorting by age group in order to find the best facility for you or your loved one. Visit **the SPINRAZA website** to view a current list of SPINRAZA treatment centers.



THE SPINRAZA AMBASSADOR PROGRAM

Many people find it helpful to talk to someone who is in a similar medical situation.

Biogen sponsors local events where caregivers, patients, and families can connect with a healthcare provider and a SPINRAZA Ambassador. A SPINRAZA Ambassador is a patient or caregiver who shares stories about his or her personal experience with SMA and SPINRAZA.

A FAM can tell you about events in the area, or you can visit **the SPINRAZA website**. From there, search by zip code or state and register to attend an event.

SELECTED IMPORTANT SAFETY INFORMATION

Increased risk of kidney damage, including potentially fatal acute inflammation of the kidney, has been observed after administration of similar medicines. Your healthcare provider should perform urine testing before you start treatment with SPINRAZA and before each dose to monitor for signs of this risk.

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BIOGEN WILL BE THERE THROUGHOUT THE SPINRAZA® (nusinersen) TREATMENT JOURNEY

Biogen is committed to helping individuals with SMA and their caregivers, and will work with you and your loved one every step of the way in the SPINRAZA treatment journey.

You should also feel empowered to become a strong advocate with the health plan and the doctor for yourself or your loved one. This can be done by working closely with the doctor's office and providing any information it may need. You can also reach out often to the health insurance plans to emphasize the need for access to treatment. Even if coverage for SPINRAZA is denied at first, there are other options available. There also are financial assistance programs that can help pay for SPINRAZA.

Remember, one program that can help navigate the SPINRAZA treatment journey is SMA360°. The SMA360° team will guide you and your loved one step by step through the process of starting SPINRAZA treatment. They will also help with health plan benefits and find sources to help to cover the cost of treatment with SPINRAZA.

We hope this guide provides helpful information about health plan choices and coverage options for SPINRAZA and SMA care. Please keep it as a resource to refer to when needed.

SOFIA // AGE 2.5
INFANTILE-ONSET (TYPE 1) SMA
TREATED WITH SPINRAZA

Individual results may vary based on several factors, including severity of disease, initiation of treatment, and duration of therapy.

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Before taking SPINRAZA, tell your healthcare provider if you are pregnant or plan to become pregnant.

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GLOSSARY OF KEY TERMS

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GLOSSARY OF KEY TERMS

Appeal: A request for a health plan to reconsider its decision to deny coverage for a specific healthcare service or product.

Benefit exclusion: Both medicines and healthcare services can be excluded from benefit coverage by the health plan. An example of this is when there is no coverage for a specific medicine in a health plan's medical policy. Another example is a limit to the number of times you or your loved one can receive a service or treatment, such as physical therapy or home healthcare.

Benefits Investigation/Verification: The research that is done to see if the health plan covers a specific medicine.

Clinical response: The effectiveness of a medical treatment, such as a drug, as measured by a change in the signs and symptoms of a medical condition.

Copayment (or copay): A set amount that a patient pays for a healthcare services covered by insurance.

Coinsurance: The share (percentage) the patient pays of the cost of a covered healthcare service.

Compassionate Allowances: An SSI program that reduces waiting time for a benefits decision by quickly identifying a disease or condition that meets the Social Security Administration's standard for disability.

Cost sharing: The portion of costs covered by insurance that is paid out of the patient's pocket, such as deductibles, coinsurance, and copayments.

Deductible: The amount a patient must pay for healthcare services before the insurance plan begins paying the healthcare costs.

Dual eligible: A person who receives assistance from both Medicare and Medicaid.

External review: A review of a plan's decision to deny coverage for or payment of a service by an independent third-party not related to the plan.

Fee-for-service (FFS): A structure in which the patient and their health plan pay a portion of the costs at each visit or service. These plans often offer more flexibility in choice of providers or hospitals, but tend to cost more. FFS is also known as indemnity insurance.

Health maintenance organization (HMO): A type of plan in which patients get care from a network of providers. The primary care doctor coordinates all of the care.

High-deductible health plan (HDHP): A healthcare plan with a higher deductible than a traditional healthcare plan. The monthly premium is usually lower, but patients pay more healthcare costs themselves (their deductible) before the insurance company starts to pay its share.

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In-network provider (or preferred provider): Doctors, hospitals, or other providers who participate in the health plan. Patients usually pay less when using an in-network provider. Some plans only pay for services when the member uses in-network providers. Other plans will pay some of the cost even if the member uses an out-of-network provider.

Insurance exchange: The insurance exchange is a government service that is also known as the Health Insurance Marketplace. It was started as a result of the Affordable Care Act to help people get affordable health insurance. The insurance exchange allows people to shop for and sign up for health insurance that is offered in each state.

Letter of Medical Necessity: A letter submitted by the doctor to the health plan that provides information to demonstrate that the requested healthcare services or supplies are needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms and meet accepted standards of care and the medical needs of the patient.

Medicaid: A health insurance program by each state that provides coverage for people with low incomes, disabilities, and special needs. People enrolled in Medicaid get their care mainly from private providers, community health centers, and managed care plans that contract with Medicaid to provide needed services.

Medical exception (ME): A medical exception is a request to use a drug due to the patient's individual situation even though the drug is not covered by the patient's health plan.

Medically necessary: Healthcare services or supplies that meet the accepted standards of care and are needed in order to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms.

Medicare: A government health insurance program that provides coverage for individuals aged 65 years or older and for those younger than 65 years who have certain disabilities.

Medicare Advantage Plan: Medicare Advantage plans, also known as Medicare Part C, are private insurance plans that are approved by Medicare. Every month, Medicare pays the private insurance company a fixed amount of money. Then that company covers patient costs.

Medigap: A Medigap policy is health insurance sold by private insurance companies to fill the "gaps" in Original Medicare plan coverage. Medigap policies help pay some of the healthcare costs that the Original Medicare plan doesn't cover.

Network: The institutions (hospitals, labs, etc), providers (doctors, etc), and suppliers the plan works with to provide healthcare services.

Out-of-network provider: A healthcare provider or facility (such as a hospital or SMA treatment center) that is not in the plan's network.

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Out-of-pocket costs: Medical expenses that are not reimbursed or covered by the insurance company.

Premium: The amount that must be paid by a family or an individual to get coverage. For some people with commercial insurance, a portion of the health plan premium is paid by their employer.

Primary Insurer (or primary payer): For people with more than 1 source of health insurance, primary insurance is their main source of coverage that pays first, unless a particular healthcare service or product is not covered.

Prior authorization (PA, preauthorization, or precertification): The requirement by a plan that, before coverage is allowed, a treatment or medication must be medically necessary.

Provider network: A group of healthcare providers (such as doctors), facilities (such as hospitals), and suppliers (such as pharmacies) that work with a health plan to provide services and products to its members.

Reauthorization: A periodic review by a health plan (usually 6 months to 1 year) to ensure that a prescribed drug is still medically necessary.

Referral: An order or permission granted by the primary care provider for a patient to receive specialty care. For example, some individuals with SMA may need a referral to see a specialist, such as a pulmonologist or an orthopedist.

Referral restriction: A requirement by some insurers, including HMO plans and Medicaid, to receive a letter, or referral, from primary care providers before approving coverage for specialty care.

Secondary/supplemental payer (or secondary/supplemental insurer): For those with more than 1 source of health insurance, this is an additional source of coverage that pays for the services or costs not covered by the primary health insurance.

Specialty pharmacy: Specialty pharmacies manage drugs that need special handling or storage. These drugs may not be available at your local pharmacy. The doctor's office will order these drugs for the patient. Also, specialty pharmacies may offer support services, such as answering questions about treatment.

US Food and Drug Administration (FDA): An agency within the US Department of Health and Human Services. The FDA is responsible for protecting the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices.

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INDICATION

SPINRAZA® (nusinersen) is a prescription medicine used to treat spinal muscular atrophy (SMA) in pediatric and adult patients.

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CLICK TO PRINT

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Biogen