

ISEMBYLD™
(apitegromab-mstn) injection
150mg/3mL

PRIOR AUTHORIZATION AND APPEALS TOOLKIT



Please see Important Safety Information on [page 3](#) and full [Prescribing Information](#).



INTRODUCTION

The Prior Authorization (PA) and Appeals Toolkit is designed to support you in navigating the PA and reauthorization submission process for ISEMBYLD. It aims to help you identify and gather all the required information and present it to the payer in a clear and complete manner.

This resource is provided for informational purposes only and does not constitute legal, regulatory, billing, coding, or reimbursement advice. Healthcare providers (HCPs) are responsible for ensuring that use of this resource complies with all applicable laws, regulations, and payer requirements.

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INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

ISEMBYLD (apitegromab-mstn) is indicated for the treatment of spinal muscular atrophy (SMA) in adults and pediatric patients 2 years of age and older who are currently receiving a survival motor neuron 2 (SMN2)-targeted treatment.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Fractures

ISEMBYLD may increase the risk of fractures, including serious fractures. Use with caution in patients with a history of low bone density or multiple fractures. In patients who experience fractures, weigh the risks and benefits of continuing ISEMBYLD.

ADVERSE REACTIONS

The most common adverse reactions (incidence $\geq 20\%$ of patients treated with ISEMBYLD and more frequent than placebo) were upper respiratory tract infections, vomiting, cough, other viral infections, headache, gastroenteritis, pharyngitis, and hypersensitivity.

USE IN SPECIFIC POPULATIONS

Pregnancy and Lactation

Based on animal data, ISEMBYLD may cause fetal harm. There are no adequate data on the developmental risk associated with the use of ISEMBYLD in pregnant women.

There are no data on the presence of ISEMBYLD in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ISEMBYLD, and any potential adverse effects on the breastfed infant.

Females and Males of Reproductive Potential

Based on animal data, ISEMBYLD may affect male and/or female reproductive function.

OVERVIEW OF BENEFITS INVESTIGATION AND SCHOLAR ROCK SUPPORTS



Initiating benefits investigation

ISEMBYLD is infused intravenously,¹ and health plans typically manage ISEMBYLD and its administration under the medical benefit rather than the pharmacy benefit.

After ISEMBYLD is prescribed, a benefits investigation can determine coverage for ISEMBYLD and its administration based on the patient's insurance plan benefits and his or her individual needs. Your patients are encouraged to enroll in our patient support program, **Scholar Rock Supports**, for assistance with this process.

Enrollment in Scholar Rock Supports

Scholar Rock Supports offers coordinated resources and personalized assistance to help patients access treatment and navigate the treatment journey:

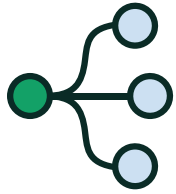
- Insurance access and benefits support
- Financial and copay assistance (for eligible patients)
- Infusion day logistical support
- Caregiver support and resources
- Education on what patients can expect with treatment

Benefits investigation – A thorough benefits investigation identifies the following:

PA and required documentation	Does the patient's health plan require PA for ISEMBYLD coverage? Does the health plan require a specific PA form or documentation (eg, Letter of Medical Necessity, prescribing information, or motor function assessment) for approval?
Medical exception	If ISEMBYLD is not covered by the patient's health plan or if PA is denied, what would be the process to seek medical exception?
Coordination of benefits	If the patient is covered by more than one health plan, which plan should be billed as primary vs secondary? Do both/all health plans have specific instructions regarding coordination of benefits for claim submission?
Site of care considerations	Does the patient's health plan require a specific site of care?
Patient's financial obligations	What is the patient's out-of-pocket cost? Might the patient be eligible for any financial assistance options via Scholar Rock Supports?
Product acquisition requirements	Does the health plan require your office to acquire ISEMBYLD from a specific specialty pharmacy? Based on the selected site of care, should ISEMBYLD be billed under medical or pharmacy benefit?
Claims submission	Does the patient's health plan require specific form(s), codes, and other documentation for claims submission?
Reauthorization	What is the authorization period? What are the reauthorization criteria and timeline?

Some health plans may apply carve-outs, exclusions, or special benefit designs that impact coverage or site of care. A benefits investigation can help identify these considerations early.

POTENTIAL PROVIDER NETWORK RESTRICTIONS



Each health plan may have a network of participating providers who have contracted to provide healthcare programs under specific terms. As a result, patients may be restricted or incentivized to seek care from in-network (or “preferred”) providers. If they do not obtain care from in-network providers, their out-of-pocket (OOP) costs could be higher or the product might not be covered at all.

For Medicaid beneficiaries, coverage is generally limited to participating providers in the specific state, and Medicaid beneficiaries may also be restricted to care from in-network providers within their state. However, Medicaid administrators may grant exceptions allowing coverage as long as medical necessity can be established and there are no in-network providers with the required expertise in the relevant state.



Your Scholar Rock **Rx Onboarding and Care Coordinator (ROCC)** can help your patients understand their insurance coverage and what to expect with ISEMBYLD treatment.

Please call **Scholar Rock Supports** at 1-833-SRRK-444 (1-833-777-5444) Monday - Friday, 8 AM - 8 PM ET for financial and copay assistance for eligible patients.

SITE OF CARE CONSIDERATIONS

Review the health plan's site of care policy to determine if there are site-specific administration requirements for ISEMBYLD

ISEMBYLD is administered via intravenous infusion. Common sites of care include the following:



- Provider's office
- Hospital outpatient infusion center
- Stand-alone infusion center
- Home infusion

If a site of care is responsible for product acquisition and billing, it should conduct a benefits investigation and obtain PA. If the patient can receive home infusion through their insurance plan, the provider should ensure that the specific home infusion provider is covered or in the preferred network under patient's health plan. **Scholar Rock Supports** can assist with home infusion services as well.



If your office does not provide infusion services, promptly refer patients to a site of care that is covered under their insurance plan.



Your Scholar Rock **Rx Onboarding and Care Coordinator (ROCC)** can help patients locate an appropriate site of care or home infusion provider. The **ROCC** can also help coordinate infusion logistics between the patient's caregiver and the site of care in preparation for the ISEMBYLD treatment visit.



Your Scholar Rock **Regional Clinical Specialist (RCS)** can help answer clinical questions regarding ISEMBYLD infusion logistics. Please call **Scholar Rock Supports** at 1-833-SRRK-444 (1-833-777-5444) Monday - Friday, 8 AM - 8 PM ET for assistance.

OBTAINING AUTHORIZATION FOR ISEMBYLD TREATMENT

Health plans often require a PA for a patient to receive ISEMBYLD. In addition, health plans may require a reauthorization for continuation of therapy after a specified period of time. Information regarding PA and reauthorization criteria and their respective timing can be found in the medical policy or on the health plan's specific PA form.

The PA process and considerations

1 Review the coverage requirements based on the patient's health plan

Note: Many health plans often require the use of plan-specific PA forms, which may include distinct documentation, site-of-care requirements, and product acquisition criteria that must be satisfied for coverage consideration. An example of possible PA criteria for ISEMBYLD is provided on the next page.

2 Fill out and ensure that all information on the PA form is accurate and complete with all requested documentation attached

Note: One of the most common reasons for denials is missing or incomplete information. Ensure documentation is complete, including chart notes documenting diagnosis, patient status, and a list of all previous or current spinal muscular atrophy (SMA) therapies.

3 Attach supplemental documentation specified by the health plan

This may include the ISEMBYLD Prescribing Information, FDA Approval Letter, relevant clinical studies, or a **Letter of Medical Necessity**, demonstrating that the treatment is FDA approved and medically necessary based on the patient's diagnosis, clinical presentation, baseline motor functional testing, duration of symptoms, and current supportive care management. The included **Letter of Medical Necessity** templates may be leveraged to provide supplemental documentation to the health plan.

4 Submit the PA request through the appropriate health plan process and provide contact information for your office

5 Check the PA status and follow up when necessary

Note: The response time may vary depending on the health plan. Remember to document the health plan representative you have spoken with, their contact information, and the PA reference number.



Your Scholar Rock **Rx Onboarding Care Coordinator (ROCC)** can provide additional educational resources and support about the PA and reauthorization process.



Please call **Scholar Rock Supports** at 1-833-SRRK-444 (1-833-777-5444) Monday - Friday, 8 AM - 8 PM ET for financial and copay assistance for eligible patients.

FDA=U.S. Food and Drug Administration.

EXAMPLE OF PA CRITERIA FOR ISEMBYLD

- ✓ Diagnosis of SMA by a physician who specializes in the treatment of SMA or is in consultation with a neurologist or a specialist¹
- ✓ Age 2 years and older¹
- ✓ Documentation that the patient is currently on an approved survival motor neuron 2 (SMN2)-targeted treatment (eg, SPINRAZA®, EVRYSDI®)¹
- ✓ Baseline clinical status has been assessed by at least one baseline assessment. Examples of baseline assessments include the following^{1,2}:
 - The Hammersmith Functional Motor Scale Expanded (**HFMSE**)
 - The Revised Upper Limb Module (**RULM**) Test
 - World Health Organization (**WHO**) motor milestone scale
 - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (**CHOP INTEND**)
 - 6-Minute Walk Test (**6MWT**)
 - Bayley Scales of Infant and Toddler Development
 - Motor Function Measure-32 Items (**MFM-32**)

These criteria are provided as an example only. Actual requirements vary by health plan.



Ensure there is clear documentation of the SMN2-targeted treatment your patient is currently receiving when submitting the PA.

MOTOR FUNCTION ASSESSMENT CONSIDERATIONS

- ! **Motor function assessments may be required** for PA and reauthorization to document disease stability or clinical response
- ! **For initial PA, document *baseline* motor function within the health plan–required timeframe prior to the first dose.** If treatment is delayed before initiation, obtain *updated baseline* scores so it reflects current status. Outdated baselines may affect how progress is evaluated for reauthorization
- ! **For reauthorization, submit the health plan–required follow-up assessments** compared with the documented baseline



Improvements in activities of daily living (ADL), as reported by the HCP, care team, or patient and caregiver, may also be documented.

AFTER PA APPROVAL

- ! **Schedule the infusion** at the health plan–approved site of care and confirm the product acquisition pathway
- ! **Ensure coordination of PA benefits** if the site of care changes between treatments to prevent coverage or claim issues
- ! **Identify reauthorization criteria and timing** outlined in the benefits investigation or health plan policy, which may include motor function assessments and documentation of clinical response or stability



For enrolled patients, contact your Scholar Rock **Rx Onboarding Care Coordinator (ROCC)** for questions related to site of care or site of care changes following PA approval. For questions related to ordering, billing, or coding, contact your **Field Reimbursement Manager (FRM)**.

HCP=healthcare provider.

REAUTHORIZATION FOR ISEMBYLD

- Health plans may require reauthorization for rare disease therapies after a defined period on therapy. Reauthorization typically requires **submission of updated documentation** to support continued coverage and is a similar process as the initial authorization
- Information regarding reauthorization criteria and timing can be found in the medical policy or on the health plan's specific PA form
- **Timely submission of reauthorization** is important to help prevent coverage gaps and treatment interruption



Start the reauthorization process early by ensuring patients are scheduled for the health plan–required assessments needed to support continued coverage.

Examples of common **reauthorization criteria** for SMA treatment:



Initial authorization criteria were met prior to ISEMBYLD initiation



Documentation that the patient continues required concomitant therapy, if applicable



Detailed documentation of positive clinical response or disease stabilization based on motor function scales and change in activities of daily living (ADL)



If a patient experiences a change in insurance coverage, or a lapse in coverage, a new PA or benefits investigation may be required, even if the patient was previously approved.

PA DENIAL AND APPEAL



If a PA is denied, review the denial letter to identify the reason(s) and the next steps, which vary by health plan, including appeal options and timelines.



For patients enrolled in **Scholar Rock Supports**, you can share the complete denial letter with the **Rx Onboarding Care Coordinator (ROCC)** to support follow-up and documentation needs. Your Scholar Rock **Field Reimbursement Manager (FRM)** can support you with complex access and reimbursement needs.



1 Determine the reason(s) for denial

Examples of top reasons for claims denial: **missing or incomplete information, incorrect codes, lack of medical necessity documentation, or determination that the patient does not meet health plan criteria or labeled indication**. If additional information is requested, submit the necessary documentation immediately.

2 Appeal preparation and submission process

An appeal is a request to the patient's health plan to reconsider and approve the requested medication. Review the health plan's **denial letter to determine the appeal process and timelines, including the following**:

- The specific form to be filled out for an appeal
- The health plan's preferred method of appeal (eg, phone, written, etc)
- Which documentation should be included (eg, appeal letter, original claims, etc)
- If an expedited review or peer-to-peer review is available and appropriate for a patient's situation

RESOURCES: **Letter of Medical Necessity** templates for initiating or continuing ISEMYLD (for HCP use) and **Letter of Appeal** templates (for HCP or patient/caregiver use). In some cases, additional supporting materials, such as a patient statement describing disease impact and daily functioning, may be included.

3 Consider a peer-to-peer review

Some health plans may allow HCPs to request a peer-to-peer review if the reason for denial is **misalignment with the clinical policy**. For this type of review, the prescribing physician may contact the health plan to discuss the clinical rationale with the reviewing Medical Director of a similar specialty.

4 Follow up

Follow up with the health plan to confirm that the appeal was received and to check on the decision.

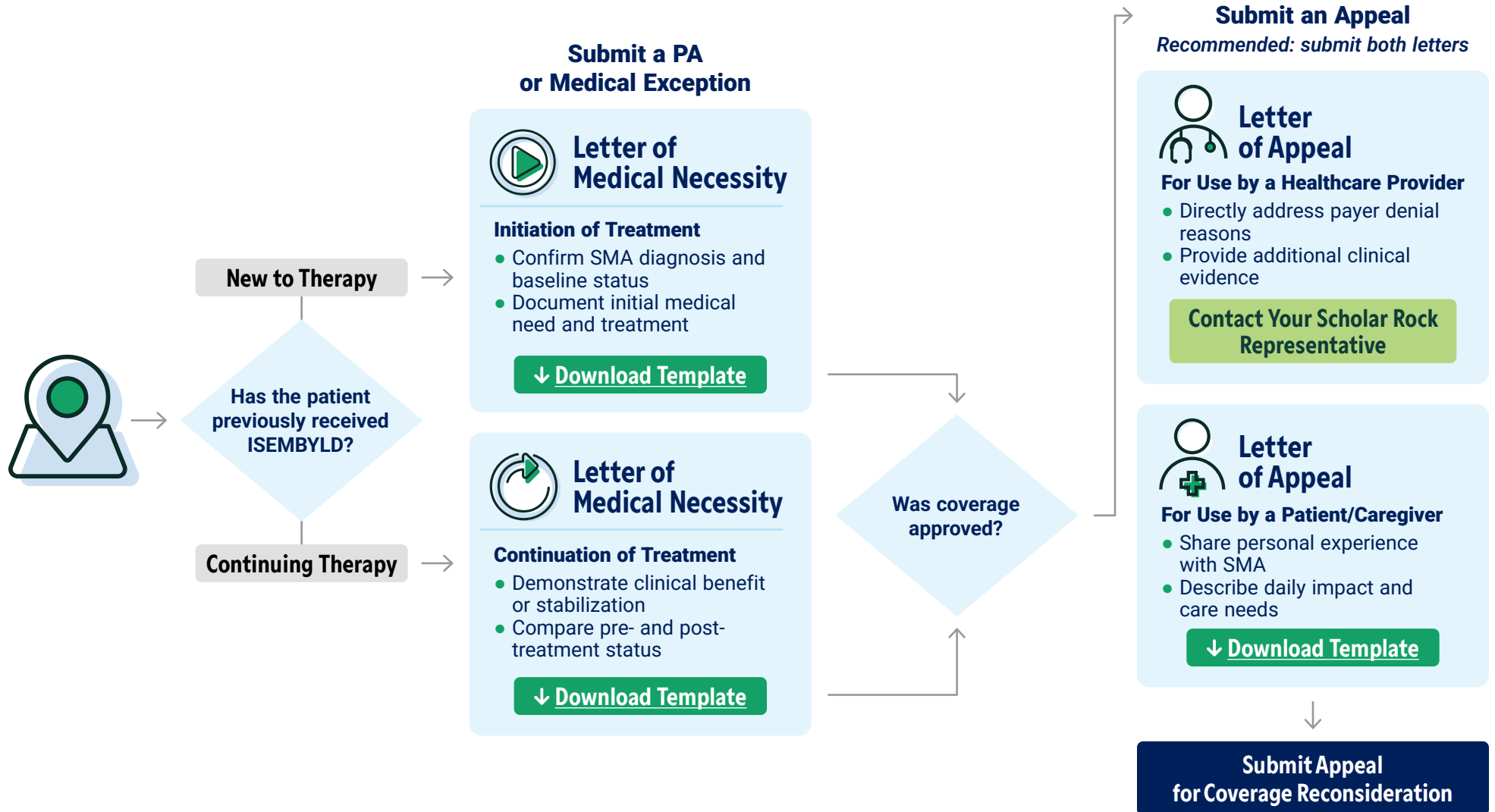
5 External review

If the internal appeals process is exhausted, an **external review** is available by independent, accredited medical professionals. External reviewers do not receive any financial incentives to perform the review, and a patient's health plan is often required by law to accept the reviewer's decision. Refer to the most recent denial letter (final internal appeal determination) for external review instructions, timelines, and any authorization requirements.

LETTER OF MEDICAL NECESSITY AND APPEAL TEMPLATES

Scholar Rock provides 4 letter templates for informational purposes to support coverage requests for patients prescribed ISEMBYLD. These resources do not replace independent medical decision-making by a prescriber.

The visual below illustrates how and when each letter may be used throughout the coverage journey, from PA through appeal, to support payer review and decision-making.



SCHOLAR ROCK REPRESENTATIVES FOR YOU, YOUR PRACTICE, AND YOUR PATIENTS

Neuromuscular Account Managers (NAMs)

Work with HCPs and key stakeholders to increase awareness, education, and engagement so appropriate patients can start and stay on treatment.

Field Reimbursement Managers (FRMs)

Support HCP offices and infusion sites as they navigate complex access and reimbursement pathways, identifying nonclinical barriers so appropriate patients can begin and maintain treatment.

Rx Onboarding and Care Coordinators (ROCCs)

A highly visible role in the SMA community and the main point of contact supporting patients throughout their treatment journey.

Regional Clinical Specialists (RCSs)

Support infusion sites and clinical staff with operational coordination, including education about Scholar Rock product preparation, administration, storage, and handling.

References

1. ISEMBYLD Prescribing Information. Scholar Rock, 2026.
2. Cigna. Nusinersen. Accessed September 11, 2026. https://static.cigna.com/assets/chcp/pdf/coveragePolicies/pharmacy/ip_0182_coveragepositioncriteria_nusinersen.pdf



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