

Mallinckrodt is here to support you and your patients treated with Acthar® Gel (repository corticotropin injection). Below are some commonly asked questions that will help you understand the referral process as well as how Acthar Patient Support can help support your patient(s), their parent(s)/caregiver(s) and you/your facility. We will be here for you and your patients and their family throughout their Acthar treatment journey.

We offer several methods to help eligible patients get access to Acthar Gel as quickly as possible, in accordance with applicable rules and regulations.

	Acthar Gel Commercial Starter Program*	Direct Purchase	The Patient's Specialty Pharmacy†	
			White Bagging	Brown Bagging
Description	The program gives eligible patients their first vial of Acthar Gel for free while the Acthar Patient Support Team works through the reimbursement process with the patient's care team‡	Hospitals purchase directly, for in-patient use only, from Acthar Gel's approved Specialty Distributor	Acthar Gel is dispensed to the patient through their Specialty Pharmacy and delivered to their treatment facility	Acthar Gel is dispensed to the patient through their Specialty Pharmacy and delivered to their home or place of convenience
Commercial Insurance Eligibility	✓	✓	✓	✓
Government Insurance Eligibility	Not eligible	✓	✓	✓
Important Contact Information	To get patients started, call 1-888-435-2284 to reach your Acthar Patient Support Team Case Manager	To order, call CuraScript at 1-877-599-7748	For more information on Specialty Pharmacy delivery options, call 1-888-435-2284 to reach your Acthar Patient Support Team Case Manager	

* **Acthar Gel Commercial Starter Program Terms and Conditions:** To be eligible, patients need to be Acthar Gel naïve, have a valid Acthar Gel prescription for Infantile Spasms, and have been verified to have commercial or private insurance. Government-insured patients are not eligible for this offering due to current government regulations. See additional terms and conditions on page 6.

†If the first vial is delivered through commercial insurance faster than through the Commercial Starter Program (CSP), then the CSP enrollment will be canceled.

‡Dispensing method depends on the patient's insurance and the hospital's policy.

INDICATION

Acthar® Gel (repository corticotropin injection) is indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.

SELECT IMPORTANT SAFETY INFORMATION

Contraindications

- Acthar should never be administered intravenously
- Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of Acthar
- Acthar is contraindicated where congenital infections are suspected in infants
- Acthar is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, or sensitivity to proteins of porcine origin

Please see additional Important Safety Information throughout. Also see full Prescribing information at www.acthar.com.

1. How do I refer a patient for Acthar® Gel (repository corticotropin injection)?

- Go to www.actharpatientsupport.com/hcp/. At this website, you can learn more about the support services that the Acthar Patient Support team can provide. At the top right of the main page you will find a button for the “Forms & Documents”. To get started, click the “Forms & Documents”, then select “Infantile Spasms” from the side tray to complete the referral form. When completed, fax the referral form to the Acthar Patient Support team along with any supporting information and/or documentation. The fax number is on the form.
- The referral form can also be accessed directly at the following URL:
https://actharpatientsupport.com/assets/files/PSR_IS_Acthar_Referral_Combos_Form.pdf

2. What can I expect from the process?

Once you send a referral to the Acthar Patient Support team (otherwise known as “the Hub”), the team reviews the referral and performs a benefit investigation. After that is complete, they will reach out to you with information on how to complete the required prior authorization (PA) for your patient’s insurance plan. They will provide you the appropriate instructions to complete and submit to the plan. It is important to remain in contact with the Hub since they will communicate with you/your team every step of the way. It is also important to provide cell/pager numbers and/or alternate contacts so that they can reach you and your team as quickly as possible to ensure any potential delays to patients gaining access to therapy are minimized.

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- The adverse effects of Acthar are related primarily to its steroidogenic effects
- Acthar may increase susceptibility to new infection or reactivation of latent infections
- Suppression of the hypothalamic-pituitary-adrenal (HPA) axis may occur following prolonged therapy with the potential for adrenal insufficiency after withdrawal of the medication. Adrenal insufficiency may be minimized by tapering of the dose when discontinuing treatment. During recovery of the adrenal gland patients should be protected from the stress (e.g. trauma or surgery) by the use of corticosteroids. Monitor patients for effects of HPA suppression after stopping treatment
- Cushing's syndrome may occur during therapy but generally resolves after therapy is stopped. Monitor patients for signs and symptoms
- Acthar can cause elevation of blood pressure, salt and water retention, and hypokalemia. Blood pressure, sodium, and potassium levels may need to be monitored
- Acthar often acts by masking symptoms of other diseases/disorders. Monitor patients carefully during and for a period following discontinuation of therapy

Please see additional Important Safety Information throughout. Also see full Prescribing information at www.acthar.com.

3. What services does Acthar Patient Support provide?

The Acthar Patient Support team provides a comprehensive support service to patients that are prescribed Acthar® Gel (repository corticotropin injection) for an approved indication, such as Infantile Spasms in children under the age of 2. This includes:

- Reimbursement support by a **Case Manager**, to assist the patient, their parents/caregivers and you/your team through what can be a complicated insurance process.
- Injection training by a **Nurse Navigator** (or reinforcement training in cases where you/your team train the parents/caregivers first) in the home/place of convenience, virtually or telephonically.
- Telephonic support to the patient's parents/caregivers from the time of referral receipt until the patient has completed their Acthar Gel treatment.
- A **Patient Assistance Program** is available for patients who qualify if their insurance denies them coverage for Acthar Gel or if they are uninsured or under-insured. (See *eligibility criteria for Patient Assistance Program on page 6.*)
- Resources and support for Spanish speaking patients and caregivers

4. What digital training resources are available to instruct my patients' caregivers on how to properly administer Acthar Gel?

- Patients' Caregivers can view an informative video covering the step-by-step treatment walkthrough of how to inject Acthar Gel at home by visiting www.actharis.com/im-infant-injection-training. The video will also cover information about preparation, injection, storage, and disposal.
- You can also download the Injection Guide, available in [English](#) or [Spanish](#).
- Support for Acthar Gel is there beyond the injection, too. [Treatment resources](#) can help.
- You can request a physical injection demonstration kit to be mailed to your office by calling the Hub at 1-888-435-2284

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd)

- Acthar can cause GI bleeding and gastric ulcer. There is also an increased risk for perforation in patients with certain gastrointestinal disorders. Monitor for signs of bleeding
- Acthar may be associated with central nervous system effects ranging from euphoria, insomnia, irritability, mood swings, personality changes, and severe depression to psychosis. Existing conditions may be aggravated
- Patients with comorbid disease may have that disease worsened. Caution should be used when prescribing Acthar in patients with diabetes and myasthenia gravis
- Prolonged use of Acthar may produce cataracts, glaucoma, and secondary ocular infections. Monitor for signs and symptoms
- Acthar is immunogenic and prolonged administration of Acthar may increase the risk of hypersensitivity reactions. Neutralizing antibodies with chronic administration may lead to loss of endogenous ACTH activity

Please see additional Important Safety Information throughout. Also see full Prescribing information at www.acthar.com.

5. My patient has commercial or private insurance only. Do you have any other programs to help my patient with their Acthar® Gel (repository corticotropin injection) prescription?

YES! There are several such programs designed for those patients in mind:

- We have the [Commercial Starter Program](#) (see *terms and conditions for the Program on page 6*). This program is designed to provide medication to eligible patients typically in 24-48 hours while the Acthar Patient Support team works to help coordinate reimbursement and subsequent shipment through a specialty pharmacy.
 - Enrollment into this program can be completed on Section 5 of the IS referral form, available online:
https://actharpatientsupport.com/assets/files/PSR_IS_Acthar_Referral_Combos_Form.pdf
- There is also a Commercial Co-pay Assistance Program that the Acthar Patient Support team can review with your patient's parents/caregivers. If eligible, the program could reduce their copay to zero dollars, up to \$25,000 per calendar year. (See *terms and conditions for the Program on page 6*.)

6. Who will dispense my patient's Acthar Gel?

Acthar Gel is dispensed by a network of Specialty Pharmacies that are uniquely equipped to manage patients with complex, rare diseases as well as products that require special handling and tight inventory management. The pharmacies that have access to Acthar Gel are Accredo, AllianceRx Walgreens Prime, BriovaRx, CVS Caremark, Humana, IngenioRx, Senderra, Special Care Pharmacy Services (in Puerto Rico) and some Walgreens Community Care Pharmacies.

7. If my institution purchases Acthar Gel from Curascript, how can the institution bill for reimbursement?

You should consult your facility's billing experts on the process of how Acthar Gel should be billed. Reimbursement rates are established by plan type, your insurance coverage and billing procedures within your facility.

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd)

- There is an enhanced effect in patients with hypothyroidism and in those with cirrhosis of the liver
- Long-term use may have negative effects on growth and physical development in children. Monitor pediatric patients
- Decrease in bone density may occur. Bone density should be monitored for patients on long-term therapy
- Pregnancy Class C: Acthar has been shown to have an embryocidal effect and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus

Please see additional Important Safety Information throughout. Also see full Prescribing information at www.acthar.com.

8. How can I get someone to come to my facility and explain all of this to me/my team?

You can follow this link <https://actharpatientsupport.com/hcp/request-a-visit/> or call 888-435-2284 to request an Access and Reimbursement Manager (ARM) to make an in person visit to discuss access and reimbursement.

9. If I want to talk to someone about the clinical aspects of Acthar® Gel (repository corticotropin injection), where do I go?

You have three options:

- If you wish to speak to someone over the phone, you may call the Mallinckrodt medical team at 1-800-778-7898
- Send an e-mail to medinfo@mallinckrodt.com
- If you wish for someone to visit your office or team, call the Hub at 1-888-435-2284 and request a visit. Depending on the nature of your request we can connect you with a Medical Science Liaison or an Access and Reimbursement Manager.

10. What information do you have on the treatment of Infantile Spasms with Acthar Gel?

There is a wealth of information on treating Infantile Spasms patients with Acthar Gel at <https://www.actharishcp.com/about-acthar>. If you have further questions, you may call the medical information line at 1-800-778-7898.

11. How do I know how to dose my Infantile Spasms patient?

To learn more about dosing with Acthar Gel, please visit <https://www.actharishcp.com/dosage-and-administration>.

12. How can I get additional Infantile Spasms supplies?

If you need additional supplies for Infantile Spasms patients, you may call or email the Acthar Patient Support team at 888-435-2284 or asaphb@ubc.com.

SELECT IMPORTANT SAFETY INFORMATION

Adverse Reactions

- Common adverse reactions for Acthar are similar to those of corticosteroids and include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite, and weight gain
- Specific adverse reactions reported in IS clinical trials in infants and children under 2 years of age included: infection, hypertension, irritability, Cushingoid symptoms, constipation, diarrhea, vomiting, pyrexia, weight gain, increased appetite, decreased appetite, nasal congestion, acne, rash, and cardiac hypertrophy. Convulsions were also reported, but these may actually be occurring because some IS patients progress to other forms of seizures and IS sometimes masks other seizures, which become visible once the clinical spasms from IS resolve

Other adverse events reported are included in the full Prescribing Information.

Please see full Prescribing information at www.acthar.com for additional Important Safety Information.

Terms and Conditions:

Acthar® Gel (repository corticotropin injection) Commercial Starter Program Terms and Conditions:

To be eligible, patients need to be Acthar Gel naïve, have a valid Acthar Gel prescription for Infantile Spasms, and have been verified to have commercial or private insurance. Government-insured patients are not eligible for this offering due to current government regulations. A patient who is participating in Medicare, Medicaid, or any government-funded healthcare plan is not eligible to participate in the Acthar Gel Commercial Starter Program. The Program is valid for one vial of Acthar Gel at a time as needed, up to four vials, prior to coverage approval by the patient's insurance. The patient will no longer receive vials under the Program when the patient receives insurance approval, a final denial of coverage, or the fourth vial. The patient may receive up to an additional three vials if the prescriber provides documentation of need and the patient has not received a final determination from the insurance company. The patient agrees not to seek reimbursement from any third-party payor for all or any part of Acthar Gel dispensed pursuant to the Program. The Program is void where prohibited by law. Mallinckrodt reserves the right to rescind, revoke, or amend the Program at any time without notice. By participating in the Program, the patient agrees to these eligibility terms and conditions.

Acthar Patient Assistance Program:

If patients do not have insurance coverage, they may be able to receive assistance options through the Acthar Patient Assistance Program*:

- Mallinckrodt provides Acthar at no cost to eligible patients with a valid, on-label prescription for Acthar who have no insurance, are underinsured, or are rendered uninsured
- Their Case Manager will transfer them to the Acthar Patient Assistance Program to determine eligibility
- This program is administered via a third-party organization
- **Acthar Patient Assistance Program eligibility criteria:**
 - Valid Acthar prescription for an FDA-approved indication
 - Permanent US resident
 - Household income at or below 700% of the Federal Poverty Level
 - Patients may be subject to random income verification to determine eligibility

Co-Pay Program Terms and Conditions:

- Patient must have a valid Acthar® Gel prescription for an FDA-approved, on-label indication.
- Patient must be a permanent US resident. Offer is good only in the United States and US Territories.
- Patient (or patient's legal representative) must be 18 years of age or older to opt into program.
- This program is valid for eligible privately and commercially insured patients.
- This program is not valid for patients covered by Medicare, Medicare D, Medicare Advantage Plans, Medicaid plans (including Medicaid patients enrolled in a qualified health plan purchased through a health insurance exchange [marketplace], TRICARE, Department of Defense (DOD), Veterans Affairs (VA), or any other state or federal medical or pharmacy benefit program.
- The Acthar Commercial Co-pay Program provides drug co-pay assistance of up to \$25,000 per calendar year for each eligible patient.
- The program covers out-of-pocket costs for Acthar® Gel only. The program will not and shall not be applied toward the cost of any other product, healthcare provider service, supply charges or other treatment costs.
- This program does not constitute prescription drug coverage or insurance and is not intended to substitute for such coverage. This program is not valid for uninsured patients and cannot be used as primary insurance.
- The offer is not valid for drug costs that are eligible to be reimbursed by private insurance plans or other health or pharmacy benefit programs, which reimburse you for the entire cost of your prescription drugs.
- Enrollment in the co-pay assistance program does not guarantee assistance. Whether an expense is eligible for the copay benefit will be determined at the time the benefit is paid. Eligible co-pay expenses must be in connection with a separately paid claim for Acthar® Gel which is otherwise covered by a private/commercial insurance plan.
- If your insurance status changes, you must notify us prior to fulfilling your next prescription of Acthar® Gel.
- This program offer is limited to 1 membership per person and is not transferable and cannot be combined with any other co-pay assistance program, free trial, discount, prescription savings card, or other offer.
- Patients should consult their insurance provider concerning any limitations that may apply to this program under their insurance policy. Patients are responsible for any co-payment or coinsurance costs above and beyond the program's annual maximum benefit.
- The program is not available where prohibited by law.
- Mallinckrodt reserves the right to rescind, revoke, or amend the co-pay assistance program at any time without notice.
- Patient will be subject to ineligibility from the Program for violation of these Terms & Conditions.