IS

Acthar® GEL
(repository corticotropin injection) 80 U/mL

For Infantile Spasms

Acthar Referral Form

FAX: 1-877-937-2284
EMAIL: intake@supportandaccess.com

Please complete and email or fax toll-free
For questions, please call: 1-888-435-2284
Monday through Friday (8:00 AM to 9:00 PM ET)
Saturday (9:00 AM to 2:00 PM ET)

PRESCRIBER INSTRUCTIONS:

1. **Have your patient's representative read page 3 (section 8): PATIENT AUTHORIZATION(S). Request that the patient's representative sign the top section** to allow Acthar Patient Support to provide a complete level of support during the approval process. **If the patient's representative would like to receive support, please have them sign the second section or provide consent at ActharConsent.com** to enroll in support and educational programs to receive additional information about the patient's condition and treatment.
2. **Complete pages 1 and 2 of the Acthar Referral Form.**
3. **Email or fax the completed Acthar Referral Form along with clinical notes, any medically relevant documentation, and copies of both the front and back of your patient's medical and prescription benefit card(s) to 1-877-937-2284 or intake@supportandaccess.com.**
4. Acthar Patient Support will process the Acthar Referral Form and contact both you and your patient's representative.
5. Prior authorization assistance will only be provided for indicated disease states. Medicare, Medicaid, and other federal or state healthcare program patients may be ineligible for certain other aspects of Acthar assistance programs.

PRESCRIBER SIGNATURE ON PAGE 1 AUTHORIZES PRESCRIPTION, CONSENT, AND STATEMENT OF MEDICAL NECESSITY

By signing page 1, I certify that Acthar® Gel is medically necessary for this patient and that I have reviewed this therapy with the patient's representative and will be monitoring the patient's treatment. I verify that the patient and Prescriber information on this enrollment form was completed by me or at my direction and that the information contained herein is complete and accurate to the best of my knowledge.

I understand that I must comply with my practicing state's specific prescription requirements, such as e-prescribing, state-specific prescription form, fax language, etc. Noncompliance with state-specific requirements could result in outreach to me by the dispensing pharmacy.

I authorize United BioSource LLC ("UBC"), the current operator of Acthar Patient Support, and other designated operators of the Program, to act on my behalf for the limited purposes of transmitting this prescription to and received by the designated Specialty Pharmacy by any means under applicable law, including via a designated third party or other operator of the Program.

I understand that representatives from the Program or UBC may contact me or my patient's representative for additional information relating to this prescription. I acknowledge and agree that this prescription may be sent to and received by the designated Specialty Pharmacy by any means under applicable law, including via a designated third party or other operator of the Program, and that no additional confirmation of receipt of prescription is required by the designated Specialty Pharmacy.

I request that company-funded Acthar Injection Training Services be arranged for my patient's representative. I understand that Acthar Injection Training Services are available for multiple visits but are NOT a home health nursing service and that I or my patient's representative may opt out of any nursing services by notifying the Acthar Patient Support Team by calling 1-800-435-2284. Patient representatives can contact their Nurse Navigator at any time about injection training.

PATIENT REPRESENTATIVE'S INSTRUCTIONS:

Your Prescriber will submit the completed Acthar Referral Form to Acthar Patient Support. After we receive the form, we will call you so we can help you get your medicine. Please be on the lookout and answer calls from 1-800, 1-888, or blocked numbers. If you have any questions, please call **1-888-435-2284** Monday through Friday from 8 AM to 9 PM ET or Saturday from 9 AM to 2 PM ET.

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URGENT!
FAX: 1-877-937-2284
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☐ SENT PRESCRIPTION DIRECTLY TO SPECIALTY PHARMACY. PLEASE ENROLL PATIENT IN ACTHAR PATIENT SUPPORT.

PHARMACY NAME: _____

Acthar Referral Form

Please complete and email or fax toll-free
For questions, please call: 1-888-435-2284
Monday through Friday (8:00 AM to 9:00 PM ET)
Saturday (9:00 AM to 2:00 PM ET)

1. PATIENT INFORMATION

Patient's representative has been notified of referral ☐ YES ☐ NO

PATIENT FIRST NAME | MIDDLE INITIAL | LAST NAME | DATE OF BIRTH | GENDER

HOME ADDRESS | CITY | STATE | ZIP

SHIPPING ADDRESS (IF NOT HOME) | CARE OF (IF NOT ADDRESSED TO PATIENT) | CITY | STATE | ZIP

HOME PHONE | MOBILE PHONE | ALTERNATE PHONE | **BEST TIME TO CALL**

EMAIL ADDRESS | **PREFERRED LANGUAGE IF NOT ENGLISH**

PATIENT REPRESENTATIVE CONTACT NAME | TELEPHONE | EMAIL | RELATIONSHIP TO PATIENT

2. INSURANCE INFORMATION (Please include copies of front and back of all medical and prescription insurance cards)

PHARMACY BENEFITS | SUBSCRIBER ID # | GROUP # | TEL #

PRIMARY MEDICAL INSURANCE | SUBSCRIBER ID # | GROUP # | TEL #

3. PRESCRIBER INFORMATION

SPECIALTY: ☐ NEUROLOGY ☐ OTHER (Please indicate on line 2 below)

PRESCRIBER FIRST NAME | MIDDLE INITIAL | LAST NAME | NPI # | STATE LICENSE #

OFFICE / CLINIC / INSTITUTION NAME | TELEPHONE | FAX | OTHER SPECIALTY

ADDRESS | CITY | STATE | ZIP

OFFICE CONTACT NAME | CONTACT TELEPHONE | CONTACT MOBILE PHONE | CONTACT EMAIL ADDRESS

4. PRESCRIPTION: ACTHAR® GEL

NDC# 63004-8710-1 — 5 mL multidose vial containing 80 USP units per mL inj

4A. ICD-10 CODE: **(REQUIRED):**_____(SEE PG 2, SEC 6 FOR **PRIMARY DIAGNOSIS CODES**).

4B. SELECT AN FDA RECOMMENDED DOSE **OR** OTHER DOSE
VISIT WWW.ACTHARHCP.COM/DOSING-AND-DURATION TO CALCULATE DOSE AND QUANTITY OF VIALS

DOSE: ☐ 75 UNITS/M² (IM) ☐ OTHER: (Specify Units or mL) _____

SCHEDULE/FREQUENCY: ☐ TWICE DAILY FOR 2 WEEKS ☐ OTHER: _____

HEIGHT:_____ ☐ in ☐ cm **WEIGHT:**_____ ☐ lb ☐ kg

QUANTITY OF 5 mL MULTIDOSE VIALS*: _____ **REFILLS*:** _____

*When using the online IS Dosing calculator to calculate quantity of 5 mL multidose vials, round up partial vials to next whole number. Order additional vials if overage is needed for wastage.

4C. TAPER INSTRUCTIONS (Attach taper schedule and provide additional instructions below, if applicable)

4D. ALLERGIES ☐ NKDA - No known drug allergies (Additional space provided on pg 2)

4E. SUPPLIES PHARMACY TO SUPPLY FOLLOWING UNLESS "OTHER" IS SPECIFIED:

- **SYRINGE:** 1 ML
- **NEEDLE FOR DRAWING:** 20 G
- **NEEDLE FOR INTRAMUSCULAR INJECTON:** 25 G, 1"
- **SHARPS CONTAINER**

PHARMACY TO DISPENSE SUFFICIENT SUPPLIES TO COMPLETE COURSE OF THERAPY. PHARMACIST MAY ELECT TO DISPENSE ALTERNATE SUPPLIES AS NECESSARY.

☐ OTHER:

5. COMMERCIAL STARTER PROGRAM (CSP)

5 mL multidose vial containing 80 USP units per mL inj

5A. ICD-10 CODE:_____Starter product is available at no cost to eligible patients for prompt access to therapy while working through the reimbursement process. Eligible patients must have a valid prescription for an FDA-approved indication, have verified commercial or private insurance, and are not participating in Medicare, Medicaid, or any government-funded healthcare plan. Full terms and conditions on pg 3.†

5B. SELECT AN FDA RECOMMENDED DOSE **OR** OTHER DOSE
VISIT WWW.ACTHARHCP.COM/DOSING-AND-DURATION TO CALCULATE DOSE AND QUANTITY OF VIALS

DOSE: ☐ 75 UNITS/M² (IM) ☐ OTHER: (Specify Units or mL) _____

SCHEDULE/FREQUENCY: ☐ TWICE DAILY FOR 2 WEEKS ☐ OTHER: _____

HEIGHT:_____ ☐ in ☐ cm **WEIGHT:**_____ ☐ lb ☐ kg

QUANTITY OF 5 mL MULTIDOSE VIALS*: _____ **REFILLS*:** _____

*When using the online IS Dosing calculator to calculate quantity of 5 mL multidose vials, round up partial vials to next whole number. Order additional vials if overage is needed for wastage.

5C. TAPER INSTRUCTIONS (Attach taper schedule and provide additional instructions below, if applicable)

5D. ALLERGIES ☐ NKDA - No known drug allergies (Additional space provided on pg 2)

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- **SHARPS CONTAINER**

PHARMACY TO DISPENSE SUFFICIENT SUPPLIES TO COMPLETE COURSE OF THERAPY. PHARMACIST MAY ELECT TO DISPENSE ALTERNATE SUPPLIES AS NECESSARY.

☐ OTHER:

OPT OUT ONLY - ACTHAR INJECTION TRAINING SERVICES

☐ **By checking here, I request to opt out of Acthar Injection Training Services for my patient.**

PRESCRIBER SIGNATURE: Please sign only ONE LINE below (by signing below you are agreeing to the Prescriber Consent section on the cover page of this document)

Brand Medically Necessary / Do Not Substitute / No Substitution / DAW / May Not Substitute — May Substitute / Product Selection Permitted / Substitution Permissible

X _____ **DISPENSE AS WRITTEN** **DATE** **OR** X _____ **SUBSTITUTIONS ALLOWED** **DATE**

Prescriber signature required for consent and to validate prescriptions. Prescriber attests that this is her/his signature. NO STAMPS. By signing, Prescriber certifies that the above is medically necessary.

ATTN: New York and Iowa providers, please submit electronic prescription. CA, MA, NC & PR: Interchange is mandated unless Prescriber writes the words "No Substitution"

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Patient Name:_____ **Date of Birth:**_____

6. DIAGNOSIS AND MEDICAL INFORMATION

DIAGNOSIS CODES: BELOW IS A LIST OF THE MOST COMMON CODES. THESE CODES HAVE BEEN PROVIDED FOR CONVENIENCE ONLY. THESE ARE NOT ALL POSSIBLE DIAGNOSIS CODES, AND NOT INTENDED TO INFLUENCE A DIAGNOSIS.

Please provide as much information as possible that corresponds with the patient's diagnosis. You may also write in the patient's diagnosis in the "OTHER DIAGNOSIS" section.

❑ **Infantile spasms (IS)**

Has diagnosis been confirmed by EEG?

❑ YES ❑ NO

Requested drug delivery date: _____

❑ EPILEPTIC SPASMS, NOT INTRACTABLE, WITH STATUS EPILEPTICUS
G40.821

❑ EPILEPTIC SPASMS, NOT INTRACTABLE, WITHOUT STATUS EPILEPTICUS
G40.822

❑ EPILEPTIC SPASMS, INTRACTABLE, WITH STATUS EPILEPTICUS
G40.823

❑ EPILEPTIC SPASMS, INTRACTABLE, WITHOUT STATUS EPILEPTICUS
G40.824

❑ OTHER:

7. RELEVANT TREATMENT HISTORY AND CONCURRENT MEDICATIONS (Including recent corticosteroid history, if applicable)

★

Therapy Name	Dose	Start Date	Stop Date (if applicable)	Explain Outcome With Detail (eg, type of outcome)

OTHER RELEVANT CLINICAL INFORMATION (INCLUDING ALLERGIES)

❑ NKDA - No known drug allergies

PRESCRIBER SIGNATURE: REQUIRED FOR DOCUMENTATION

I verify that the Patient and Prescriber information on this enrollment form was completed by me or at my direction and that the information contained herein is complete and accurate to the best of my knowledge. I certify that Patient's representative has agreed in writing to be contacted by Program administrators or UBC and be furnished with Program or other information or materials.

x

NAME SIGNATURE DATE

IS

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Patient Name:_____ Date of Birth:_____

8. PATIENT AUTHORIZATION(S)

Patient Consent to allow Acthar Patient Support Team to work together with your insurance provider, pharmacy, advocacy organization and others to provide support on your behalf.

By signing this authorization, I authorize my physician(s), my health insurance company and my pharmacy providers (collectively, "Designated Parties") to use, disclose, and redisclose to Mallinckrodt ARD LLC ("Mallinckrodt"), the distributor of Acthar, and its agents, authorized designees and contractors, including Mallinckrodt reimbursement support personnel and United BioSource LLC ("UBC") or any other operator of Acthar Patient Support on behalf of Mallinckrodt (collectively, "Manufacturer Parties"), health information relating to my medical condition, treatment and insurance coverage (my "Health Information") in order for them to (1) provide certain services to me, including reimbursement and coverage support, patient assistance and access programs, medication shipment tracking, and home injection training, (2) provide me with support services and information associated with my Acthar therapy, (3) serve internal business purposes, such as marketing research, internal financial reporting and operational purposes, and (4) carry out the Manufacturer Parties' respective legal responsibilities.

Once my Health Information has been disclosed to Manufacturer Parties, I understand that it may be redisclosed by them and no longer protected by federal and state privacy laws. However, Manufacturer Parties agree to protect my Health Information by using and disclosing it only for the purposes detailed in this authorization or as permitted or required by law.

I understand that I may refuse to sign this authorization and that my physician and pharmacy will not condition my treatment on my agreement to sign this authorization form, and my health plan or health insurance company will not condition payment for my treatment, insurance enrollment or eligibility for insurance benefits on my agreement to sign this authorization form. I understand that my pharmacies and other Designated Parties may receive payment in connection with the disclosure of my Health Information as provided in this authorization. I understand that I am entitled to receive a copy of this authorization after I sign it.

I may revoke (withdraw) this authorization at any time by mailing a letter to Acthar Patient Support, 680 Century Point, Lake Mary, FL 32746. Revoking this authorization will end further disclosure of my Health Information to Manufacturer Parties by my pharmacy, physicians, and health insurance company when they receive a copy of the revocation, but it will not apply to information they have already disclosed to Manufacturer Parties based on this authorization. I also know I may cancel my enrollment in a patient support program at any time in writing by contacting Mallinckrodt via fax at 1-877-937-2284 or by calling Acthar Patient Support at 1-888-435-2284. This authorization is in effect for 5 years unless a shorter period is provided for by state law (MARYLAND HEALTHCARE PROVIDERS, under Maryland Code HG § 4-303(b)(4) this authorization expires ONE YEAR from the date of signature) or until the conclusion of any ongoing coverage support, whichever is longer, once I have signed it unless I cancel it before then.

THIS SECTION MUST BE COMPLETED IN ITS ENTIRETY, INCLUDING DATE

➡ x

PATIENT NAME OR LEGAL REPRESENTATIVE	PATIENT OR LEGAL REPRESENTATIVE SIGNATURE	IF LEGAL REPRESENTATIVE, RELATIONSHIP TO PATIENT	DATE

Patient Consent to receive additional information from Mallinckrodt such as education on your disease and Acthar.

I authorize Mallinckrodt and its partners to use, disclose, and/or transfer the personal information I supply (1) to contact me and provide me with informational and marketing materials and clinical trial opportunities related to my condition or treatment by any means of communication, including but not limited to text, email, mail, or telephone; (2) to help Mallinckrodt improve, develop, and evaluate products, services, materials, and programs related to my condition or treatment; (3) to enroll me in and provide me with Acthar-related programs and services that I may select or refuse at any time; (4) to disclose my enrollment and use of these services to my prescriber and insurers; and (5) to use my information that cannot identify me for scientific and market research. This authorization will remain in effect until I cancel it, which I may do at any time in writing by contacting Mallinckrodt via fax at 1-877-937-2284 or by calling Acthar Patient Support at 1-888-435-2284. I may request a copy of this signed authorization.

THIS SECTION MUST BE COMPLETED IN ITS ENTIRETY, INCLUDING DATE

➡ x

PATIENT NAME OR LEGAL REPRESENTATIVE	PATIENT OR LEGAL REPRESENTATIVE SIGNATURE	IF LEGAL REPRESENTATIVE, RELATIONSHIP TO PATIENT	DATE

Scan the QR Code below to save the Acthar Patient Support phone number to your mobile device's contacts (see steps below).

STEP 1
Open the camera on your mobile device

STEP 2
Hold your camera over the QR code to scan

STEP 3
Save your Acthar Patient Support Team information to your contacts

If patient's representative is not present to sign the form, send them to

ActharConsent.com

and have patient's representative sign electronically.

†**ACTHAR GEL COMMERCIAL STARTER PROGRAM TERMS & CONDITIONS:** Eligible patients for this Program must meet the following criteria: have a valid prescription for the selected FDA-approved indication of infantile spasms in infants and children under 2 years of age, have verified commercial or private insurance, and are not participating in Medicare, Medicaid, or any government-funded healthcare plan. This Program is valid for one vial of Acthar Gel at a time as needed; however, the patient will no longer receive Acthar Gel under this Program when the patient receives insurance approval or a final denial of coverage. The patient agrees not to seek reimbursement from any third-party payer for all or any part of Acthar Gel dispensed pursuant to this Program. This Program is void where prohibited by law. Mallinckrodt reserves the right to rescind, revoke, or amend this Program at any time without notice. By participating in this Program, the patient agrees to these terms and conditions.

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IMPORTANT SAFETY INFORMATION

Contraindications

Acthar is contraindicated:

- For intravenous administration
- In infants under 2 years of age who have suspected congenital infections
- With concomitant administration of live or live attenuated vaccines in patients receiving immunosuppressive doses of Acthar
- 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

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 axis 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. Monitor blood pressure and sodium and potassium levels
- Acthar often acts by masking symptoms of other diseases/disorders. Monitor patients carefully during and for a period following discontinuation of therapy
- Acthar can cause gastrointestinal (GI) bleeding and gastric ulcer. There is also an increased risk for perforation in patients with certain GI disorders. Monitor for signs of perforation and 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. Cases of anaphylaxis have been reported in the postmarketing setting. Neutralizing antibodies with chronic administration may lead to loss of endogenous ACTH and Acthar activity
- There may be 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 in patients on long-term therapy

Adverse Reactions

- Commonly reported postmarketing adverse reactions for Acthar include injection site reaction, asthenic conditions (including fatigue, malaise, asthenia, and lethargy), fluid retention (including peripheral swelling), insomnia, headache, and blood glucose increased
- The most common adverse reactions for the treatment of infantile spasms (IS) are increased risk of infections, convulsions, hypertension, irritability, and pyrexia. Some patients with IS progress to other forms of seizures; IS sometimes masks these seizures, which may become visible once the clinical spasms from IS resolve

Pregnancy

- Acthar may cause fetal harm when administered to a pregnant woman

Please see accompanying full Prescribing Information for additional Important Safety Information or visit https://www.actharhcp.com/Static/pdf/Acthar-PI.pdf.

INDICATION AND USAGE

Acthar Gel is indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.

Mallinckrodt Pharmaceuticals