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

Acthar Gel Enrollment/Prescription Form
Please complete and email or fax toll-free
Phone: 888-435-2284
FAX: 877-937-2284
EMAIL: intake@supportandaccess.com

1 PATIENT & PRESCRIBER

PATIENT INFORMATION

Last Name:
First Name and Middle Initial:
Date of Birth:
Mobile Phone: Phone:
Preferred Language (other than English):

Address:
City:
State: Zip Code:
Email:
Caregiver:

Allergies: ☐ NKDA - No known drug allergies

Patient Sex: ☐ Male ☐ Female

(Additional space provided on pg 2)

INSURANCE INFORMATION

*Include a copy of the front and back of the patient's prescription benefit and insurance card(s) when submitting this form **OR** complete the fields to the right.*

Pharmacy Benefit Provider:	Primary Medical Insurance:
Subscriber #:	Subscriber #:
Group #:	Group #:
Phone #:	Phone #:

PRESCRIBER INFORMATION

HCP Name: NPI #: Tax ID #:
Specialty: Office Contact Name:
Address: Contact Phone: Extension:
City: State: Zip Code: Contact Fax:
State License Number: Contact Email:

2 PRESCRIPTION: ACTHAR® GEL
SUBCUTANEOUS INJECTION

Preferred Specialty Pharmacy:

PLEASE ENROLL PATIENT IN ACTHAR PATIENT SUPPORT

ICD-10 Code (Required):

☐ MULTIPLE SCLEROSIS **G35** ☐ OTHER OPTIC NEURITIS **H46.8**

NOTE: PROVIDED TO THE LEFT ARE THE **2 MOST COMMON CODES**; FOR OTHER PRIMARY DIAGNOSIS CODES, PLEASE SEE PAGE 2

Acthar Gel Single-Dose Pre-filled SelfJect™ Injector
Subcutaneous Injection

☐ 80 Units/mL NDC 63004-8711-4

Once daily for:

☐ 8 Days ☐ 12 Days ☐ 16 Days ☐ 20 Days

☐ Other:

Number of Refills:

OR

Acthar Gel 5 mL multi-dose vial (80 USP Units/mL)
Subcutaneous Injection

☐ 80 Units/mL NDC 63004-8710-1 ☐ Other: Units

Once daily for:

☐ 10 Days ☐ 15 Days ☐ 20 Days

☐ Other:

Number of Refills:

VIAL SUPPLIES: Pharmacy to supply the following unless "OTHER" is specified

- Syringe: 1 ML
- Needle for Drawing: 20 G
- Needle for Injection: 25 G, 5/8"
- Sharps Container
- OTHER:

Pharmacy to dispense sufficient supplies to complete course of therapy. Pharmacist may elect to dispense alternate supplies as necessary.

OTHER INSTRUCTIONS: (Attach taper schedule and provide additional instructions, if applicable)

3 HISTORY OF CORTICOSTEROID USE

When submitting Prior Authorization, please include chart note documentation to support history of steroid use.

PLEASE CHECK ALL THAT APPLY:

A corticosteroid **was** tried with the following response(s):

☐ Corticosteroid use failed, but same response not expected with Acthar
☐ Patient hypersensitive or allergic to corticosteroids
☐ Patient intolerant of corticosteroids
☐ Other:
As evidenced by:

OR

A corticosteroid **was not** tried due to the following reason(s):

☐ Corticosteroid use is contraindicated for this patient
☐ Intravenous access is not possible for this patient
☐ Patient has known intolerance to corticosteroids
☐ Other:
As evidenced by:

PRESCRIBER SIGNATURE: Please sign only ONE LINE below (by signing below you are agreeing to the Prescriber Consent section on page 4 of this document)

Brand Medically Necessary / Do Not Substitute / No Substitution / DAW / May Not Substitute

X
Dispense as Written Date

or

May Substitute / Product Selection Permitted / Substitution Permissible
There is no A/B rated substitute for Acthar. This space is required by certain states

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."
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).

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DIAGNOSIS AND MEDICAL INFORMATION

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

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 (e.g., ICD-10 code, how Acthar is being prescribed for use, and organ involvement). You may also write in the patient's diagnosis in the "OTHER DIAGNOSIS" section.

☐ Multiple sclerosis (Must check one)

Is Acthar to be used to treat an acute exacerbation?

☐ YES
☐ NO
☐ OTHER: _____

ONSET OF ACUTE EXACERBATION DATE: _____

☐ MULTIPLE SCLEROSIS
G35

☐ NEUROMYELITIS OPTICA [DEVIC]
G36.0

☐ OTHER OPTIC NEURITIS
H46.8

☐ OTHER DERMATOPOLYMYOSITIS WITH MYOPATHY
M33.12

☐ OTHER DERMATOPOLYMYOSITIS WITHOUT MYOPATHY
M33.13

☐ POLYMYOSITIS, ORGAN INVOLVEMENT UNSPECIFIED
M33.20

☐ POLYMYOSITIS WITH MYOPATHY
M33.22

☐ DERMATOPOLYMYOSITIS,UNSPECIFIED WITHOUT MYOPATHY
M33.93

☐ OTHER DIAGNOSIS:
_____

RELEVANT TREATMENT HISTORY (Especially corticosteroid history. Attach additional case notes as necessary.)

THERAPY NAME	DOSE	START DATE	STOP DATE (if applicable)	EXPLAIN OUTCOME WITH DETAIL (eg. type of outcome)

RELEVANT TREATMENT HISTORY (Including Allergies)

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 my patient has agreed in writing to be contacted by Program administrators or UBC and be furnished with Program or other information or materials.

X _____
Signature

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FOR COMPLETION BY PATIENT OR THEIR REPRESENTATIVE

PATIENT AUTHORIZATION(S)

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

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 is not present to sign the form, send them to
Acthar Consent.com
and have them sign electronically.

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RESOURCE PAGE. DO NOT NEED TO FAX BACK.

PRESCRIBER INSTRUCTIONS

1. **Complete pages 1 and 2 of the Acthar Enrollment/Prescription Form.**
2. **Have your patient read page 3, PATIENT AUTHORIZATION(S). Request that the patient sign both sections** to allow Acthar Patient Support to provide a complete level of support both during the approval process and after starting treatment. **Alternatively, direct the patient to provide this consent at ActharConsent.com.** Tell your patient to expect a call and save the Acthar Patient Support number, 1-888-435-2284.
3. **Email or fax pages 1, 2, and 3 of the completed Enrollment/Prescription 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 intake@supportandaccess.com or 1-877-937-2284.**

Acthar Patient Support will process the Enrollment/Prescription Form and contact both you and your patient by phone, text, or email. Prior authorization assistance will only be provided for FDA-approved indications. 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 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 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. 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 may opt out of any nursing services by notifying the Acthar Patient Support Team by calling 1-888-435-2284. Patients can contact their Nurse Navigator at any time about injection training.

PATIENT INSTRUCTIONS

Your Prescriber will submit the completed Acthar Enrollment/Prescription 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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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

INDICATIONS AND USAGE

- Acthar Gel is indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown Acthar to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease.
- Acthar Gel is indicated for severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation.

Mallinckrodt Pharmaceuticals