NEPH

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

☐ SENT PRESCRIPTION DIRECTLY TO SPECIALTY PHARMACY. PLEASE ENROLL PATIENT IN ACTHAR PATIENT SUPPORT.

PHARMACY NAME: _____

FAX: 1-877-937-2284
Acthar Referral Form
Please complete Referral Form and fax toll-free
TEL: 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 has been notified of referral ☐ YES ☐ NO

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

HOME ADDRESS | CITY | STATE | ZIP

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

HOME PHONE | MOBILE | ☐ **OK TO TEXT** | **BEST TIME TO CALL**

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

ALTERNATIVE CONTACT NAME | RELATIONSHIP TO PATIENT | TELEPHONE

2. INSURANCE INFORMATION (PLEASE INCLUDE COPIES OF CARDS)

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

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

3. HEALTHCARE PROVIDER (HCP) INFORMATION

HCP FIRST NAME | HCP MIDDLE INITIAL | HCP LAST NAME | NPI # | GROUP NPI # (IF APPLICABLE) | STATE LICENSE #

SPECIALTY: ☐ NEPHROLOGY ☐ OTHER (PLEASE INDICATE) _____

FACILITY NAME | TELEPHONE | FAX

ADDRESS | CITY | STATE | ZIP

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

PREFERRED METHOD OF COMMUNICATION: ☐ OFFICE PHONE ☐ MOBILE PHONE ☐ FAX ☐ EMAIL ☐ TEXT ☐ NO PREFERENCE PREFERRED CONTACT TIME: _____

4. PRESCRIPTION: ACTHAR® GEL
NDC# 63004-8710-1 5 mL multidose vial containing 80 USP units per mL

4A. PLEASE SELECT FDA-APPROVED RECOMMENDED DOSE OR OTHER DOSE

FDA-APPROVED RECOMMENDED DOSE
☐ 40 UNITS 2 TIMES A WEEK
☐ 80 UNITS 2 TIMES A WEEK

☐ **OTHER DOSE:** _____ ☐ UNITS ☐ mL

SCHEDULE/FREQUENCY: _____

ROUTE OF ADMINISTRATION: ☐ INTRAMUSCULAR ☐ SUBCUTANEOUS

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

4B. TAPER INSTRUCTIONS

ADDITIONAL SPECIAL INSTRUCTIONS, TITRATION OR TAPER DOSE, IF APPLICABLE:

☐ SEE ATTACHED TAPER SCHEDULE FOR ADDITIONAL TAPER INSTRUCTIONS

4C. ICD-10 CODE: _____

PRIMARY DIAGNOSIS CODES ON PAGE 2, SECTION 6

4D. IDENTIFYING SUPPLIES IS MANDATORY FOR A COMPLETE PRESCRIPTION

SYRINGE SIZE:
☐ 1 mL ☐ 3 mL ☐ Other: _____
☐ 1 box of 100 ☐ Other: _____

NEEDLE SIZE FOR DRAWING:
☐ 20 G needle, 1" ☐ Other: _____
☐ 1 box of 100 ☐ Other: _____

NEEDLE SIZE FOR INJECTION:
☐ 23 G needle, 5/8" ☐ 23 G needle, 3/4" ☐ 23 G needle, 1"
☐ 1 box of 100 ☐ Other: _____

SUPPLY REFILLS: _____ **SHARPS CONTAINER:** _____

5. PRESCRIPTION, CONSENT, AND STATEMENT OF MEDICAL NECESSITY: HCP SIGNATURE REQUIRED

ACTHAR INJECTION TRAINING SERVICES

☐ **By checking here, 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. Patients can contact their Nurse Navigator at any time about injection training.**

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 healthcare provider 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 perform a preliminary assessment of benefit verification for this patient and furnish information requested by the patient's insurer that is available on this form. I understand that insurance verification is ultimately the responsibility of the provider and third-party reimbursement is affected by a variety of factors. While UBC tries to provide accurate information, they and Mallinckrodt make no representations or warranties as to the accuracy of the information provided.

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 the designated Specialty Pharmacy receive this prescription via a designated third party, the Program, and that no additional confirmation of receipt of prescription is required by the designated Specialty Pharmacy.

HCP Prescriber Signature - Please sign only ONE LINE below (please print out and provide a wet signature as not all Specialty Pharmacies accept digital signatures)

▶ _____ **OR** ▶ _____

DISPENSE AS WRITTEN | DATE | 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.

Please see Important Safety Information on page 4.

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

6. DIAGNOSIS AND MEDICAL INFORMATION

DIAGNOSIS CODES

Please check all diagnosis codes that correspond with patient's diagnosis. Below is a list of common ICD-10 codes. You may also write in the patient's diagnosis in the "OTHER" section.

❑ **Kidney Transplant Patient**

❑ GLOMERULAR DISEASE IN SYSTEMIC LUPUS ERYTHEMATOSUS
M32.14

❑ NEPHROTIC SYNDROME WITH MINOR GLOMERULAR ABNORMALITY
N04.0

❑ NEPHROTIC SYNDROME WITH FOCAL AND SEGMENTAL GLOMERULAR LESIONS
N04.1

❑ NEPHROTIC SYNDROME WITH DIFFUSE MEMBRANOUS GLOMERULONEPHRITIS
N04.2

❑ NEPHROTIC SYNDROME WITH DIFFUSE MESANGIAL PROLIFERATIVE GLOMERULONEPHRITIS
N04.3

❑ NEPHROTIC SYNDROME WITH OTHER MORPHOLOGIC CHANGES
N04.8

❑ OTHER:

Please indicate etiology:

❑ Focal segmental glomerulosclerosis (FSGS)
❑ IgA nephropathy (IgAN)
❑ Lupus nephritis (LN)
❑ Membranous nephropathy (MN)
❑ Other:

7. HISTORY OF CORTICOSTEROID USE (IF APPLICABLE) PLEASE ADD DETAILS IN SECTION 9 BELOW.

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: _____

OR

A corticosteroid **was not** tried due to the following response(s):
❑ Corticosteroid use is contraindicated for this patient
❑ Intravenous access is not possible for this patient
❑ Patient has known intolerance to corticosteroids
❑ Other:_____

8. CONCURRENT MEDICATIONS

9. RELEVANT TREATMENT HISTORY (INCLUDING RECENT STEROID HISTORY. ATTACH ADDITIONAL CASE NOTES AS NECESSARY.)

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

OTHER RELEVANT CLINICAL INFORMATION (INCLUDING ALLERGIES)

HCP SIGNATURE: REQUIRED FOR DOCUMENTATION

I verify that the patient and healthcare provider 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.

NAME SIGNATURE DATE

Please see Important Safety Information on page 4.

For completion by patient or their representative

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

10. 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 disclose 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 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

▶ _____ _____ _____ _____

PATIENT NAME OR LEGAL REPRESENTATIVE | PATIENT 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 healthcare providers 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.

▶ _____ _____ _____ _____

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

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

ActharConsent.com

and have them sign electronically.

Acthar Patient Support
TEL: 1-888-435-2284
FAX: 1-877-937-2284

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

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
- 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
- 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

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

INDICATIONS AND USAGE

Acthar® Gel (repository corticotropin injection) is indicated for:

- Inducing a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus
- Monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
- The treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown Acthar Gel 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
- Treatment of 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
- The treatment of symptomatic sarcoidosis
- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus
- Treatment during an exacerbation or as maintenance therapy in selected cases of dermatomyositis (polymyositis)
- Adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); ankylosing spondylitis

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

Please see full Prescribing Information for additional Important Safety Information.

Mallinckrodt Pharmaceuticals