

Acthar Gel Enrollment/Prescription Form

Please complete and email or fax toll-free

Phone: 888-435-2284 FAX: 877-937-2284 FMAIL: intake@sur

PATIENT & PRESCRIBER PATIENT INFORMATION	(repository corticotrop	oin injed	ction) 80 U/mL			FAX: 877-937-2284 EMAIL: intake@sup	portandaccess	.com
Last Name:		Ad	dress:					
First Name and Middle Initial:		Cit	V:					
Date of Birth:		-	ate: Zip Co	ode.				
N. I.I. Di			Email:					
Preferred Language (other than English):		Ca	aregiver:					
Allergies: NKDA - No known drug allergies (Additional space provided on pg 2)						Patient Sex:	Male	Fema
INSURANCE INFORMATION	Pharmacy Benefit Provider:			Primary M	ledical In	surance:		
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.	Subscriber #:		Subscriber		r#:			
	Group #:		Group #:					
PRESCRIBER INFORMATION	Phone #:		Phone #:					
HCP Name:		NE	DI #-		Tax ID #	4.		
Specialty:			Office Contact Name:					
Address:		Со	ntact Phone:		Extension:			
City: State:	Zip Code:	Со	Contact Fax:					
State License Number:		Со	Contact Email:					
SUBCUTANEOUS INJECTION ICD-10 Code (Required):	(SEE PG 2 FOR PRIMARY DIAGNO	OSIS CO	DES)					
Other: Number of Refills: Number of Refills:			Other:	Units ry 24 hours	follo	SUPPLIES: Physing unless "OT yringe: 1 ML eedle for Drawing eedle for Injection harps Container THER: macy to dispense suffice of therapy. Pharma alte supplies as necession."	THER" is sp : 20 G : 25 G, 5/8" icient supplies to cist may elect to	ecified
THER INSTRUCTIONS: (Attach taper schedule and pro	The Acthar Ge	l Comm	nercial Starter Program is					
ICD-10 Code (Required): Acthar Gel Single-Dose Pre-filled SelfJect™ Injector Subcutaneous Injection		ılti-dos	is and conditions apply.		VIAL	_ SUPPLIES: PI	narmacy to	supply the
, , , , , , , , , , , , , , , , , , , ,			Units Other: Units			following unless "OTHER" is specified Syringe: 1 ML		
		o oniis	Other.	OTIILS		eedle for Drawing	: 20 G	
Frequency:	Frequency:		40.	04:		eedle for Injection		
Every 72 hours Every 48 hours Every 24	hours Every 72 hours	E	very 48 hours Ever	y 24 hours		harps Container	0, 0, 0	
Other:	Other:					THER:		
Number of Refills:	Number of Refills:				Pharr cours	macy to dispense suff e of therapy. Pharma ate supplies as neces	cist may elect to	to complete o dispense
OTHER INSTRUCTIONS: (Attach taper schedule and pro	vide additional instructions, if applic	cable)						
RESCRIBER SIGNATURE: Please sign only ONE	E LINE below (by signing below vo	ou are a	agreeing to the Prescribe	er Consent se	ection on a	page 4 of this doc	ument)	
Brand Medically Necessary / Do Not Substitute / No Substitution	<u>```</u>		May Substitute / Product There is no A/B rated sul	Selection Perr	mitted / Su	bstitution Permissib	le	
X		or	X					
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. 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).



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 Date of Birth:_

DIAGNOSIS AND MEDICAL INFORMATION

	`		,	
D-4:-		. NI.		
Patie	n	: Na	ame:	

Is this for a Kidney Transplant Patient					
GLOMERULAR DISEASE IN SYSTEMIC LUPUS ERYTHEMATOSUS M32.14 TUBULO-INTERSTITIAL NEPHROPATHY IN SYSTEMIC LUPUS ERYTHEMATOSUS M32.15	□ NEPHROTIC SYNDROME WITH D GLOMERULONEPHRITIS N04.5 □ NEPHROTIC SYNDROME WITH D N04.6		 UNSPECIFIED NEPHRITIC SYNDROME WITH DIFFUSE MESANGIOCAPILLARY GLOMERULONEPHRITIS N05.5 UNSPECIFIED NEPHRITIC SYNDROME WITH DENSE DEPO DISEASE N05.6 UNSPECIFIED NEPHRITIC SYNDROME WITH DIFFUSE CRESCENTIC GLOMERULONEPHRITIS N05.7 UNSPECIFIED NEPHRITIC SYNDROME WITH OTHER MORPHOLOGIC CHANGES N05.8 UNSPECIFIED NEPHRITIC SYNDROME WITH UNSPECIFIED MORPHOLOGIC CHANGES N05.9 		
ACUTE NEPHRITIC SYNDROME WITH DIFFUSE MEMBRANOUS GLOMERULONEPHRITIS NO0.2	NEPHROTIC SYNDROME WITH D GLOMERULONEPHRITIS N04.7	IFFUSE CRESCENTIC			
RECURRENT AND PERSISTENT HEMATURIA WITH OTHER MORPHOLOGIC CHANGES NO2.8	□ NEPHROTIC SYNDROME WITH O N04.8 □ NEPHROTIC SYNDROME WITH U CHANGES				
CHRONIC NEPHRITIC SYNDROME WITH DIFFUSE MEMBRANOUS GLOMERULONEPHRITIS N03.2 NEPHROTIC SYNDROME WITH MINOR GLOMERULAR	N04.9 UNSPECIFIED NEPHRITIC SYNDF ABNORMALITY	ROME WITH MINOR GLOMERULAR			
ABNORMALITY N04.0 NEPHROTIC SYNDROME WITH FOCAL AND SEGMENTAL GLOMERULAR LESIONS	N05.0 UNSPECIFIED NEPHRITIC SYNDE GLOMERULAR LESIONS N05.1	ROME WITH FOCAL AND SEGMENTAL	PROTEINURIA, UNSPECIFIED R80.9 OTHER DIAGNOSIS:		
N04.1 NEPHROTIC SYNDROME WITH DIFFUSE MEMBRANOUS GLOMERULONEPHRITIS N04.2	UNSPECIFIED NEPHRITIC SYNDE GLOMERULONEPHRITIS N05.2 UNSPECIFIED NEPHRITIC SYNDE		Please indicate etiology: Focal segmental glomerulosclerosis (FSGS) IgA nephropathy (IgAN) Lupus nephritis (LN)		
NEPHROTIC SYNDROME WITH DIFFUSE MESANGIAL PROLIFERATIVE GLOMERULONEPHRITIS N04.3 NEPHROTIC SYNDROME WITH DIFFUSE ENDOCAPILLARY	PROLIFERATIVE GLOMERULONE N05.3 UNSPECIFIED NEPHRITIC SYNDF ENDOCAPILLARY PROLIFERATIV	PHRITIS ROME WITH DIFFUSE	Membranous nephropathy (MN) Other:		
PROLIFERATIVE GLOMERULONEPHRITIS N04.4 IISTORY OF CORTICOSTEROID USE (if applicable). Plea	N05.4				
LEASE CHECK ALL THAT APPLY:					
corticosteroid was tried with the following response(s): Corticosteroid use failed, but same response not expected with Ac Patient hypersensitive or allergic to corticosteroids Patient intolerant of corticosteroids Other:	thar 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:			
CONCURRENT MEDICATIONS					
RELEVANT TREATMENT HISTORY (Including rece	nt corticosteroid history. Att	ach additional case notes a			
THERAPY NAME DOSE	START DATE	STOP DATE (if applica	ble) EXPLAIN OUTCOME WITH DETAIL (eg. type of outcome)		
RELEVANT TREATMENT HISTORY (Including receill) LLERGIES: NKDA - No known drug allergies	nt corticosteroid history. Atta	ch additional case notes as	s necessary.)		

Signature



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

FOR COMPLETION BY PATIENT OR THEIR REPRESENTATIVE

PATIENT AUTHORIZATION(S)

Date of Birth: Patient Name:

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





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



PATIENT NAME OR LEGAL REPRESENTATIVE



PATIENT OR LEGAL REPRESENTATIVE SIGNATURE

IF LEGAL REPRESENTATIVE, RELATIONSHIP TO PATIENT

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





Open the camera on your mobile device



Hold your camera over the QR code to scan



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.

ACTHAR GEL COMMERCIAL STARTER PROGRAM TERMS & CONDITIONS: Eligible patients for this Program must meet the following criteria: have a valid prescription for the FDA-approved indication of inducing a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus, 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. Other terms and conditions apply. See actharhcp.com/csp-terms for full details.



RESOURCE PAGE, DO NOT NEED TO FAX BACK.

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

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.



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

RESOURCE PAGE. DO NOT NEED TO FAX BACK.

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 to induce a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

