ACTHAR START FORM GUIDE

Instructions for submitting a complete and accurate Start Form.

This guide contains a pack of Acthar Start Forms created for your specialty area. While Start Forms are tailored to specific disease areas, any form can be used for any indication.

Indications

H.P. Acthar® Gel (repository corticotropin injection) is an adrenocorticotropic hormone (ACTH) analogue used for:

- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic 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 H.P. 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
- Inducing a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus
- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic dermatomyositis (polymyositis)
- The treatment of symptomatic sarcoidosis
- 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
- 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

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 origins

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
COMPLETING THE ACTHAR START FORM

1. Fill out patient information, noting the days and times patient is likely to be available for a phone call from the Acthar Hub. An alternative contact name should be added in case patient cannot be reached.

2. Complete insurance information. Include copies of insurance card.

3. Fill in healthcare provider (HCP) information, including preferred method of contact and most convenient times.

4. Fill in important/critical prescription details.
   - Include ICD-10 code from page 2, section 6. Additional codes are available on the back of the form for your convenience
   - Rx guidance based on indication is on pages 6 and 7 of this guide
   - Dosing, frequency, route of administration, quantity, refills, and supply order are required fields
   - Initial and date if you would like to request Acthar Injection Training Services for your patient

5. Sign and date to initiate the Rx.

On the Neurology Start Form, section 4 (Prescription) includes additional information for writing a prescription for those specific indications.
   - For IS weight-based dosing, a dosing calculator is available at www.actharihcp.com/acthar-dosing-calculator or in the iTunes App Store
   - For IS, attach taper schedule and check the box

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**THE PRESCRIPTION**

**COMPLETING THE ACTHAR START FORM**

<table>
<thead>
<tr>
<th>1. PATIENT INFORMATION</th>
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<tbody>
<tr>
<td>Patient has been notified of cohort</td>
<td>YES</td>
</tr>
<tr>
<td>PRIMARY MEDICAL INSURANCE</td>
<td>SUBSCRIBER ID #</td>
</tr>
<tr>
<td>(PLEASE INCLUDE COPIES OF CARDS)</td>
<td></td>
</tr>
<tr>
<td>HOME PHONE</td>
<td>MOBILE</td>
</tr>
<tr>
<td>SHIPPING ADDRESS (IF NOT HOME ADDRESS)</td>
<td>CARE OF (IF NOT ADDRESSED TO PATIENT)</td>
</tr>
<tr>
<td>CITY</td>
<td>STATE</td>
</tr>
</tbody>
</table>

**SECONDARY MEDICAL INSURANCE  | SUBSCRIBER ID # | GROUP # | TEL # |
| (PLEASE INCLUDE COPIES OF CARDS) |
| HOME PHONE | MOBILE |
| SHIPPING ADDRESS (IF NOT HOME ADDRESS) | CARE OF (IF NOT ADDRESSED TO PATIENT) |
| CITY | STATE | ZIP |

**SPECIALTY:**

- Neurology
- Dermatology
- Gastroenterology
- Pulmonology
- Other (PLEASE INDICATE) ___________________________________________________________________________________________

**PHARMACY NAME:** ________________________________

**PROVIDER SIGNATURE:** ____________________________

**ACTHAR INJECTION TRAINING SERVICES**

- Please sign ONE LINE below
  - Prescriber signature required for consent and to validate prescriptions. Prescriber confirms that this is his/her signature. NO STAMPS.

**ACCOUNT CODE:** ___________

**SKU:** ___________

**ACTHAR H&I® GEL**

**NCDB 63004-8710-1** 5 mL multidose vial containing 80 USP units per mL

**PRIMARY DIAGNOSIS CODES ON PAGE 2, SECTION 6**

<table>
<thead>
<tr>
<th>CODE</th>
<th>IC 10 CODE</th>
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<tbody>
<tr>
<td>121</td>
<td>E854.8</td>
</tr>
<tr>
<td>121</td>
<td>E854.8</td>
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</tbody>
</table>

**ACTHAR INJECTION SERVICES**

- By initiallying here (original required), I request that company-funded Acthar Injection Training Services be arranged for my patient. I understand that Acthar Injection Training Services are for one instruction visit only and NOT a home health nursing service. I also understand that all reasonable efforts will be made to schedule the Acthar Injection Training Services within 2 weeks of the patient’s receipt of Acthar. Please contact your Designated Specialty Pharmacy for any additional information.

**ktor@acthar.com**

**HUB TELEPHONE:** 1-888-435-2284

**FAX:** Monday through Friday 8:00 AM to 9:00 PM ET

**EMAIL**

**PREFERRED LANGUAGE IF NOT ENGLISH**

**OK TO TEXT**

**SHARPS CONTAINER:**

**Monday through Friday (8:00 AM to 9:00 PM ET)**

**Saturday (9:00 AM to 2:00 PM ET)**

**Toll-free telephone:** 1-888-435-2284

**Toll-free FAX:** 1-888-435-2294

Please see Important Safety Information throughout and accompanying full Prescribing Information.
Completing the Acthar Start Form Continued

6. Diagnosis and medical information

- An updated list of ICD-10 codes has been added and continues on the back of the Start Form. However, the back of the form does not need to be faxed to the Acthar Hub. If you are using an ICD-10 code from the list on the back, write the code under “OTHER” on the front side of the form.
- Forms can be used for any indication by writing the code in the “OTHER” area.
- Please add organ involvement if relevant to indication.
- If using the Nephrology Start Form, check the box to indicate the patient has had a kidney transplant.

The Acthar Start Form is submitted to payers with the Prior Authorization to validate the need for therapy for your patient. Including the information on this page is important to ensure a complete referral form.

7-9. Relevant treatment history and clinical outcomes

- Include all current or past treatments used to treat the condition for which Acthar is being prescribed.
- Note dose, duration, dates used, and outcome of therapy.
- If therapy failed or patient discontinued, record reason why.

Sign and date and include any other relevant medical information. This form is for clinical documentation purposes.

If you would prefer filling out forms online to print and fax, visit acthar.com/healthcare-professional

Case Manager: ____________________________
Phone number: __________________________
Email address: ____________________________
10. **Patient authorization.**

**Your patient’s signature:**
- Allows him or her to take advantage of enhanced Access and Reimbursement Manager support
- Allows the Specialty Pharmacy to share information about your patient’s case back to the Acthar Support Team

**Education and support authorization.**
By having your patient sign, it allows the Acthar Hub to automatically enroll your patient into patient support and educational programs, including but not limited to receiving additional information about their condition and/or their treatment.

It also allows them to take part in surveys that can help shape the programs that are available to Acthar patients.

If the patient is not present in the office to sign, email them the ActharConsent.com URL, and they can sign electronically.

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**For completion by patient or their representative**

**Patient Name:** ____________________________  **Date of Birth:** __________

**10. PATIENT AUTHORIZATIONS**

**Patient Consent to allow Acthar 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 the following parties, on my behalf and for my benefit, to disclose to Mallinckrodt ARD Inc. ("Mallinckrodt"), the distributor of Acthar, and its agents, authorized designers and contractors, including Multicare Health, reimbursement support personnel and United BioSource LLC ("UBS") or any other operator of the Acthar Hub 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, collect, and maintain information on 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) some internal business purposes, such as marketing objectives, internal financial reporting and operational purposes, and (4) comply with the Manufacturer Parties’ respective legal responsibilities.

**Once my Health Information has been disclosed to Manufacturer Parties, I understand that it may be re-disclosed 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 if I 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 can request a copy of this authorization at any time.

I may revoke (withdraw) this authorization at any time by mailing a letter to the Acthar Hub, 255 Technology Park, Lake Mary, FL 32746. Repealing this authorization will end further disclosure of my Health Information to Manufacturer Parties for my pharmacy, physician, and health insurers defined as below, but 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 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.

Please see Important Safety Information throughout and accompanying full Prescribing Information.
**ASK YOUR ACCESS AND REIMBURSEMENT MANAGER OR CASE MANAGER FOR THE ELECTRONIC APPEALS KIT**

**REQUEST THE ELECTRONIC APPEALS KIT**

Includes a letter of medical necessity template to appeal a denial for coverage for Acthar.

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### Instructions for Completing a Custom Letter of Medical Necessity

When a payer denies access, a complete Letter of Medical Necessity (LMN) will help explain the healthcare provider’s rationale and clinical decision for choosing H.P. Acthar® Gel (repository corticotropin injection).

**Help the payer understand your patient’s situation by providing the following information:**

- Patient demographics
- Reason for denial and provider response
- Medical history, including diagnosis, severity of disease (including organs affected), and current and/or previously used treatments
- Tests performed and any relevant outcomes
- Reason for prescribing Acthar
- Expected outcome if Acthar is approved or denied
- Relevant information about Acthar, such as the indication, potential mechanism of action, and published articles that support the patient’s need for Acthar treatment
- Expert status, specialist credentials, or provider experience with Acthar

**It is also important to convey to payers that:**

1. Acthar has an FDA-approved indication for the patient
2. Acthar is not a steroid and is believed to work differently than steroids
3. Acthar has published data to support use in symptomatic sarcoidosis

**Acthar is an adrenocorticotropic hormone (ACTH) analogue used for the treatment of symptomatic sarcoidosis.**

Keep in mind that 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.

**Potential Mechanism of Action (MOA)**

Acthar is not a corticosteroid and has a different mechanism of action. Acthar is a melanocortin peptide that is known to bind to melanocortin receptors (MCRs), having both potential steroid-independent immunomodulatory and anti-inflammatory properties and steroid-dependent properties through cortisol release. Acthar is believed to have steroid-independent properties when binding to MC1R, MC3R, MC4R, and MC5R sites and steroid-dependent (anti-inflammatory) properties when binding to MC2R. Acthar potentially provides a different way to impact various cells.\(^1\)\(^2\)

*While the exact mechanism of action of Acthar is unknown, further investigation is being conducted. This information is based on nonclinical data and the relationship to clinical benefit is unknown.*

**Published Data**

Clinical data demonstrate that Acthar treatment is effective in symptomatic pulmonary and extra-pulmonary sarcoidosis patients who failed usual therapy because of progressive symptomatic disease despite immunosuppressive therapy and/or excessive toxicity with current treatment.

In a prospective, single-blind study (N=18) (study attached), treatment with Acthar was associated with a significant reduction in the prednisone dose for the full 24 weeks of the study. Despite withdrawal of prednisone, patients had significant improvement in pulmonary function and chest imaging. Acthar therapy was associated with improved health-related quality of life and less fatigue. The most common side effects were anxiety and fluid retention.\(^3\)

In a retrospective study (N=47), 93% of patients treated with Acthar for ≥3 months had an improved or stable target organ response. Of the 27 patients receiving prednisone at initiation of Acthar, 24 patients reduced prednisone dosage by more than 50%. The most commonly observed adverse events included peripheral edema and agitation.\(^4\)

The efficacy and safety results presented may not be representative of the overall patient population. Patients may have been on multiple medications. The clinical outcomes may not be solely attributable to Acthar.

**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

Please see additional Important Safety Information on next page and accompanying full Prescribing Information.
• Acthar Gel injection can be self-administered, which gives patients the flexibility to take it at home or wherever is best for them.
• Acthar is a gel when refrigerated. At room temperature it changes to liquid form, ready for injection.
• The highly purified gel formulation is designed to provide a prolonged release of medication after injection.
• Acthar should not be given intravenously. Prolonged use may lead to adrenal insufficiency or recurrent symptoms, which make it difficult to stop treatment. It may be necessary to taper the dose and increase the injection interval to gradually discontinue Acthar.
• Acthar should be kept refrigerated (36°-46°F or 2°-8°C) between uses.
• Injection training by a licensed nurse is available at no cost to patients through the Acthar Hub.

### Multiple Sclerosis Relapse

**Injection:** Subcutaneous (SC) or intramuscular (IM)
**Dose:** 80-120 units (U)
**Schedule:** Daily for 2-3 weeks

**Example Rx:**
- Inject 120 U (1.5 mL) SC or IM QD for 2-3 weeks
- Quantity of multidose vials: 7
- Refills: 0

### Nephrology

**Acthar Label Recommended Dosing**

**Injection:** Subcutaneous or intramuscular
**Dose:** 40-80 units (U)
**Schedule:** Every 24-72 hours

**Example Rx:**
- Inject 80 U (1 mL) SC or IM every 24-72 hours
- Quantity of multidose vials: 5
- Refills: 0
- Inject 80 U (1 mL) SC BIW for 6 months
- Quantity of multidose vials: 2
- Refills: 5

Experts have endorsed a dose and duration for Acthar therapy of 80 units twice weekly for 6 months, based on multiple studies. After recognizing that no standardized treatment guidelines exist for managing proteinuria in nephrotic syndrome (NS) due to heterogeneity of diseases/etiologies, a team of leading experts conducted an evidence-based, systematic review to address the need to evaluate all treatments for NS, including the appropriate dosing regimen for Acthar. The review utilized the Delphi Panel Methodology, a scientific research technique that was designed for expert opinions to address important clinical questions.

The limitations of the Delphi method include a lack of guidance and agreed-upon standards regarding interpretation and analysis of results. In addition, generalizations are limited and another panel may reach different conclusions.

### Infantile Spasms

**Injection:** Intramuscular
**Dose:** 75 U/m² (FDA-recommended dosing)
**Schedule:** Twice daily for 2 weeks with a gradual taper of an additional 2 weeks to avoid adrenal insufficiency

The dose of Acthar is typically calculated using the Mosteller formula for determining body surface area (BSA). To calculate initial dosing, tapered dosing, and vial count, an IS Dosing Calculator is available online at www.actharishcp.com/acthar-dosing-calculator and at the iTunes App Store.

Acthar should never be administered intravenously. Prolonged use of Acthar may produce cataracts, glaucoma, and secondary ocular infections. Monitor for signs and symptoms.

### 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-axis (HPA) 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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
### Rheumatology

<table>
<thead>
<tr>
<th>Indication</th>
<th>Rheumatic Disorders</th>
<th>Additional Dosing From Clinical Experience With Acthar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>Acthar Prescribing Information¹</td>
<td>Retrospective case series (N=5)⁵ and open-label proof-of-concept study (N=10)⁶</td>
</tr>
<tr>
<td>Injection</td>
<td>Subcutaneous or intramuscular</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>Dose</td>
<td>40-80 units (U)</td>
<td>80 units (1 mL)</td>
</tr>
<tr>
<td>Schedule</td>
<td>Every 1-3 days</td>
<td>Twice weekly or once weekly for 12 weeks⁵ or twice weekly for 24 weeks⁶</td>
</tr>
</tbody>
</table>

**Rheumatic Disorders Example Rx:**
Inject 40 U (0.5 mL) SC or IM every 24-72 hours
Quantity of multidose vials: 3
Refills: 5

**SLE Example Rx:**
Inject 80 U (1 mL) SC or IM every 24-72 hours
Quantity of multidose vials: 6
Refills: 5

### 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 origins

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¹ Acthar Prescribing Information
⁵ Retrospective case series (N=5)
⁶ Open-label proof-of-concept study (N=10)
⁷ Prospective, open-label study
⁸ Open-label study
⁹ Prospective, open-label study

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**Sarcoidosis¹**

| Injection: | Subcutaneous or intramuscular |
| Dose:      | 40-80 units (U)                |
| Schedule:  | Every 1-3 days                 |

**Example Rx:**
Inject 80 U (1 mL) SC or IM every 24-72 hours
Quantity of multidose vials: 6
Refills: 5
Warnings and Precautions (cont’d)

- 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, and 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.
- 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, 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 mask 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 accompanying full Prescribing Information for additional Important Safety Information.

References

1. H.P. Acthar® Gel (repository corticotropin injection) Prescribing Information, Mallinckrodt ARD, Inc.