

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

Patient Support

REFERRAL GUIDE INCLUDES INFORMATION ABOUT:

- Acthar Referral Form
- Flexible Dosing
- Prior Authorizations
- Appeals Kit
- Patient Resources

INDICATIONS

Acthar[®] Gel is indicated for:

- Treatment during an exacerbation or as maintenance therapy in selected cases of dermatomyositis (polymyositis)
- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus
- 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
- Symptomatic sarcoidosis
- 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
- Inducing a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus
- 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
- Monotherapy for the treatment of infantile spasms in infants and children under 2 years of age

SELECT 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

Please see additional Important Safety Information throughout and full [Prescribing Information](#).

Completing the Acthar® Combo Referral Form

Instructions for submitting a complete and accurate Acthar Combo Referral Form

Note: The RHEUM Acthar Combo Referral Form is being used as the example; the Acthar Combo Referral Form for your specific therapeutic area may differ.

Prescriber consent language

- By signing this consent language, the Prescriber is: 1) agreeing to follow state-specific compliance guidance, 2) authorizing the HUB (UBC) to do a benefit verification for the patient, and 3) allowing the HUB to contact them or the patient to verify or complete the information required.

Front Cover



Prescription Referral Form questions?
Contact your Immunology Sales Specialist

Or call **1-888-435-2284** to speak with your Case Manager.
Monday through Friday, 8 AM to 9 PM ET and Saturday, 9 AM to 2 PM ET

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-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

2 Please see additional Important Safety Information throughout and full [Prescribing Information](#).

The prescription

1. Patient information

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

2. Insurance information

- Complete insurance information. Include copies of front and back of all medical and prescription insurance cards.

3. Prescriber information

- Fill in Prescriber information, including preferred method of contact and most convenient times.

4. Prescription: Acthar Gel

- Fill in important/critical prescription details
- If applicable, include ICD-10 code from page 2, section 6. Additional codes may be pulled from the Appendix page(s), if applicable.
- Dosing, frequency, route of administration, quantity, refills, and supply order are required fields. Include taper instructions and/or allergies, if applicable.

5. Commercial starter program (for patients who qualify)

- Fill in important/critical prescription details for patients who are new to Acthar. If applicable, include ICD-10 code from page 2, section 6. Additional codes may be pulled from the Appendix page(s), if applicable.
- Dosing, frequency, route of administration, refills, and supply order are required fields. Include taper instructions, if applicable.

Page 1

Prescriber signature

- Sign and date to initiate the Rx. By signing, you are agreeing to the Prescriber Consent section on the cover page of this document.

Acthar injection training services

- Check box to request Acthar Injection Training Services for your patient.

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Completing the Acthar® Combo Referral Form (cont'd)

Diagnosis and medical information for use with payers

Note: The RHEUM Acthar Combo Referral Form is being used as the example; the Acthar Combo Referral Form for your specific therapeutic area may differ.

6. Diagnosis and medical information

- This is a list of common ICD-10 codes. If applicable, a full list may be pulled from the Appendix page(s); however, the Appendix pages do not need to be faxed to Acthar Patient Support. If you are using an ICD-10 code that does not appear here but rather from the Appendix page(s), write the code under "OTHER DIAGNOSIS" in this section 6.

How Acthar is prescribed for use

- If diagnosis is psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis, or ankylosing spondylitis, please indicate how Acthar is being used.

Organ involvement

- Please select the organ(s) involved.

7. History of corticosteroid use

- If applicable, please check all boxes that apply. Details should be added in section 9 below.

8. Concurrent medications

- Include all concurrent medications used to treat the condition for which Acthar is being prescribed.

9. Relevant treatment history

- Include all past treatments (including recent steroid history) 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.

Other relevant clinical information

- Include other relevant clinical information (including allergies); if no known drug allergies, please check the "NKDA" box.

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Patient Name: _____ Date of Birth: _____

6. DIAGNOSIS AND MEDICAL INFORMATION

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). Below is a list of common ICD-10 codes. A full list of diagnosis codes can be found in the Appendix - Pages (i) through (iv). You may also write in the patient's diagnosis in the "OTHER DIAGNOSIS" section.

DIAGNOSIS CODES

<input type="checkbox"/> ARTHROPATHIC PSORIASIS, UNSPECIFIED L40.50	<input type="checkbox"/> SYSTEMIC LUPUS ERYTHEMATOSUS, ORGAN OR SYSTEM INVOLVEMENT UNSPECIFIED M32.10	<input type="checkbox"/> POLYMYOSITIS, ORGAN INVOLVEMENT UNSPECIFIED M33.20
<input type="checkbox"/> OTHER PSORIATIC ARTHROPATHY L40.89	<input type="checkbox"/> GLOMERULAR DISEASE IN SYSTEMIC LUPUS ERYTHEMATOSUS M32.14	<input type="checkbox"/> POLYMYOSITIS WITH MYOPATHY M33.22
<input type="checkbox"/> RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF MULTIPLE SITES WITHOUT ORGAN OR SYSTEM INVOLVEMENT M05.79	<input type="checkbox"/> SYSTEMIC LUPUS ERYTHEMATOSUS, UNSPECIFIED M32.9	<input type="checkbox"/> OTHER DIAGNOSIS:
<input type="checkbox"/> RHEUMATOID ARTHRITIS, UNSPECIFIED M06.9	<input type="checkbox"/> OTHER DERMATOMYOSITIS WITH MYOPATHY M33.12	

HOW ACTHAR IS PRESCRIBED FOR USE

If diagnosis is psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis, or ankylosing spondylitis, Acthar is being used as (select one below):

Adjunctive therapy for short-term administration to tide the patient over an acute episode or exacerbation

Low-dose maintenance therapy (in selected cases)

If diagnosis is systemic lupus erythematosus or dermatomyositis/polymyositis, Acthar is being used as (select one below):

During an exacerbation

Maintenance therapy (in selected cases)

Other:

ORGAN INVOLVEMENT

<input type="checkbox"/> Lungs	<input type="checkbox"/> Skin and tissues	<input type="checkbox"/> Brain and nervous system	<input type="checkbox"/> Spleen	<input type="checkbox"/> Salivary glands	<input type="checkbox"/> Other:
<input type="checkbox"/> Lymph nodes	<input type="checkbox"/> Eyes	<input type="checkbox"/> Bones, joints, cartilage, ligaments, tendons and muscles	<input type="checkbox"/> Liver	<input type="checkbox"/> Sinuses	
<input type="checkbox"/> Heart			<input type="checkbox"/> Kidneys and urinary tract		

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:

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 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)

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

NAME: _____ SIGNATURE: _____ DATE: _____

Please see Indications and Important Safety Information on page 4. Please see accompanying full Prescribing Information or visit <https://www.actharhcp.com/Static/pdf/Acthar-Pi.pdf>

Page 2

Prescriber signature

- Sign and date. This is for clinical documentation purposes.

If you would prefer filling out forms online to print and fax, visit Actharhcp.com or Actharconsent.com to provide consent.

Case Manager: _____

Phone Number: _____

Email Address: _____

4 Please see additional Important Safety Information throughout and full [Prescribing Information](#).

Patient authorizations

10. Patient authorizations

Your patient's signature:

- Allows them 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 Patient Support Team.

EDUCATION AND SUPPORT AUTHORIZATION

- By having your patient sign, it allows the Acthar Patient Support Team to automatically enroll your patient into patient support and educational programs, including but not limited to receiving additional information about their condition and/or 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.

Fax completed forms
1-877-937-2284



Be prepared for follow-up.

Your dedicated Case Manager at Acthar Patient Support will contact both your office and your patient.

CALL 1-888-435-2284 IF YOU HAVE ANY QUESTIONS.

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

- 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

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Patient Name: _____ Date of Birth: _____

10. PATIENT AUTHORIZATION(S)

For completion by patient or their representative

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Your patient's signature:

- Allows them to take advantage of enhanced Access and Reimbursement Manager support.
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- It also allows them to take part in surveys that can help shape the programs that are available to Acthar patients.

11. 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, 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

PRESENTER NAME OR LEGAL REPRESENTATIVE: _____ PATIENT SIGNATURE: _____ IF LEGAL REPRESENTATIVE, RELATIONSHIP TO PATIENT: _____ DATE: _____

THIS SECTION MUST BE COMPLETED IN ITS ENTIRETY, INCLUDING DATE

PRESENTER NAME OR LEGAL REPRESENTATIVE: _____ PATIENT SIGNATURE: _____ IF LEGAL REPRESENTATIVE, RELATIONSHIP TO PATIENT: _____ DATE: _____

If patient is not present in the office to sign the form, send them to ActharConsent.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 a selected FDA-approved indication of systemic lupus erythematosus, dermatomyositis/polymyositis, rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis; have not used Acthar GEL (currently or in the past), 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 visit 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, revise, 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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Dosing Information



Acthar® Gel offers flexible dosing, with a recommended 40-80 units every 1-3 days across multiple indications. In MS, flexible dosing is also available, with a recommended 80-120 units daily for 2-3 weeks.

Recommended dosing from the label¹

For RA, SLE, DM/PM, PsA, symptomatic sarcoidosis, nephrotic syndrome, and ophthalmic diseases: 40 to 80 units (0.5 to 1 mL) given intramuscularly or subcutaneously every 1 to 3 days.*†

For MS relapse: 80 to 120 units (1 to 1.5 mL) given intramuscularly or subcutaneously daily for 2 to 3 weeks.*†

For IS: 150 units/m² divided into twice daily intramuscular injections of 75 units/m² over a 2-week period.*†

You can download the IS Dosing Calculator from the Apple App Store or Google Play Store.

- Acthar Gel is administered as a self-injection or by a caregiver, giving patients the flexibility to take it at home or wherever is best for them
- Acthar Gel is a gel preparation designed to provide a prolonged release of medication after injection

DM/PM=dermatomyositis/polymyositis; IS=infantile spasms; MS=multiple sclerosis; PsA=psoriatic arthritis; RA=rheumatoid arthritis; SLE=systemic lupus erythematosus.

*Acthar Gel is provided as a 5-mL multidose vial containing 80 USP units per mL.

†It may be necessary to taper the dose or increase the injection interval to gradually discontinue treatment.

‡Dosing should then be gradually tapered over a 2-week period to avoid adrenal insufficiency.

Dosage and frequency should be individualized according to the medical condition, severity of the disease, and initial response of the patient¹

Additional dosing from clinical experience with Acthar Gel

Indication	Source	Injection route	Dose*	Schedule†
RA ²	Phase 4, two-part, multicenter, randomized withdrawal study (N=259)	Subcutaneous	80 units (1 mL)	Twice weekly for 12 to 24 weeks
DM/PM ³	Prospective, open-label proof-of-concept study (N=10) [§]	Subcutaneous	80 units (1 mL)	Twice weekly for 24 weeks
Symptomatic sarcoidosis ⁴	Retrospective chart review (N=47)	Subcutaneous or intramuscular	40 to 80 units (0.5 to 1 mL)	Twice weekly for ≥6 months
Nephrotic syndrome ⁵⁻¹¹	Multiple clinical datasets	Subcutaneous	80 units (1 mL)	Twice weekly for 6 months
Keratitis ¹²	Phase 4, multicenter, open-label study (N=36)	Subcutaneous	80 units (1 mL)	Twice weekly for 12 weeks

Funding to support some of these studies was provided by Mallinckrodt Pharmaceuticals.

This chart does not include all studies available. These studies are subject to various limitations.

[§]Ten of the 11 enrolled patients completed the study. One patient dropped out due to heart block unrelated to the study drug and was not included in the efficacy analysis, as she did not complete the minimum 8 weeks of the study drug required for outcome assessment per study protocol.

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

- 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

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Patient Support

Acthar® Patient Support

With Acthar Patient Support, a dedicated team of experts is ready to help.

Immunology Sales Specialists

Your Sales Specialist will be able to answer questions about completing and submitting your Referral Form.

Access and Reimbursement Managers (ARMs)

Your ARM is your key resource, providing reimbursement education and local area support throughout the referral process.

Nurse Navigators

The Nurse Navigator serves as a supplemental support system for your patients. Nurse Navigators will never provide medical advice, but they can help patients understand the administration of Acthar Gel, fit Acthar Gel into their routine, and address any concerns or anxiety they may have about treatment.*

Case Managers

Your Case Manager is your patients' key access resource, helping to coordinate the reimbursement process (prior authorizations and appeals) as well as any additional services that your patient may be eligible for and would like to take advantage of. Additional services include, but are not limited to, assistance program support and injection training coordination.

*Nurse Navigators do not give medical advice and will direct patients to healthcare professionals for any treatment-related questions, including further referrals.

Prior Authorizations (PAs)

When a PA for Acthar Gel is required by the health insurance company, verbal PAs or ePAs may offer a higher success rate and faster turnaround time than faxed PAs.

Work with your Access and Reimbursement Manager (ARM) and/or Case Manager (CM) to determine the preferred method to submit a PA.



Verbal PA

When available, a verbal PA offers many potential benefits, including:

- Eliminating or reducing paperwork, faxes, and callbacks
- Real-time answers to questions
- Less physician involvement needed down the road
- No scribing errors
- Most importantly, reduced process time, which may allow patients to get on therapy sooner



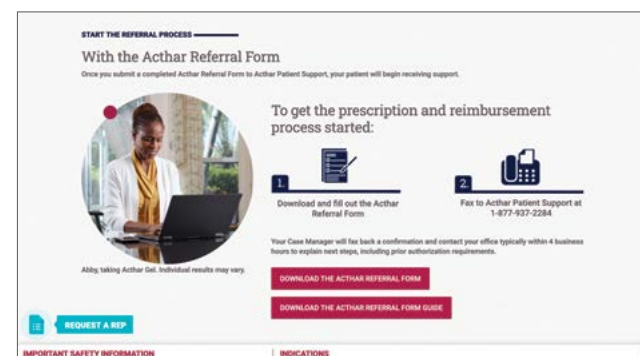
Electronic PA (ePA)/Faxed PA

There are a number of portals you may use to submit an electronic PA, such as CoverMyMeds.

Instructions:

- To initiate the PA process, fax the Acthar Referral Form to Acthar Patient Support, and make sure your email address is on the form
- ePAs may offer a higher success rate and faster turnaround time than faxed PAs. If an ePA is available, you will receive an email with a link to the ePA portal and a personal identification number (PIN)
- Click on the link and enter your national provider identifier (NPI) and PIN where indicated
- Once inside the portal, you will be able to electronically complete and submit the prior authorization
- If the submission is not immediately approved, expect to receive approval or denial after only 12 hours

Acthar Referral Forms
are available at
[Actharhcp.com/
referral-forms](https://actharhcp.com/referral-forms)



SELECT IMPORTANT SAFETY INFORMATION

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

Call **1-888-435-2284**
to speak with a Case Manager
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Saturday, 9 AM to 2 PM ET

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Appeals Kit

When a patient's insurance provider denies coverage for Acthar® Gel, the Appeals Kit simplifies the process for you to create and submit a customized Letter of Medical Necessity (LMN).



Appeals Kits are available across all therapeutic areas and include:

Step-by-step instructions

detail how to complete the LMN template.

LMN checklist

lists critical information to include in an effective LMN.

LMN templates

provide sample language for you to customize when addressing an insurance denial.

Supporting resources

are available such as clinical trials, consensus documents, and publications to support why the Acthar Gel prescription may be medically necessary and may be included as part of the response to the health plan's denial.

Acthar Gel Prescribing Information is included as a resource.

Patient Resources



If an appeal is denied, there are resources available to help patients and their caregivers raise their voices, team up with their doctor, and write an appeals letter.

All are available to download at Acthar.com/resources
Spanish resources can also be found on the website.



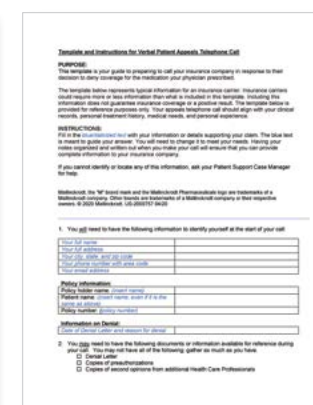
Patient Bill of Rights



Patient Appeal Discussion Guide



Appeals Letter Template



Patient Appeals Verbal Template

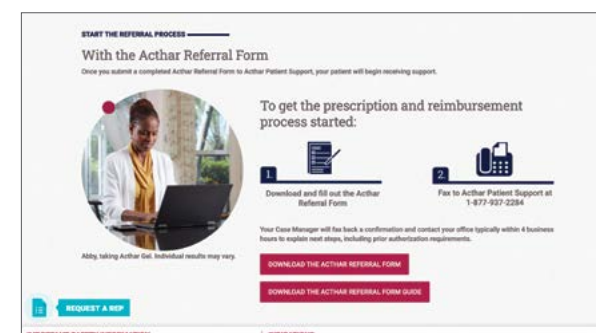


Nurse Navigator Leave Behind



Acthar Gel Patient Brochure

Additional resources are available to help patients start and continue treatment with Acthar Gel. Contact your Case Manager or ARM to order copies for your practice.



Acthar Patient Support at Actharhcp.com/support

From prescription to delivery, Acthar Patient Support is with you and your patients every step of the way.

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Assistance Options



Acthar Patient Support works closely with your office throughout the insurance approval process, keeping patients informed along the way. If assistance is needed, the following options may be available:

Your patients may be eligible for our \$0 co-pay offer*

If your patients have commercial or private insurance, they may be able to enroll in the **Acthar Gel Commercial Co-pay Program** and pay as little as \$0 for their Acthar Gel prescription. The program provides the following:

- **As little as \$0 co-pay for eligible patients, up to \$15,000 per calendar year** (see Terms and Conditions below)
- Convenient online enrollment via the new co-pay website

Your patients can enroll themselves in the Acthar Gel Commercial Co-pay Program at [Acthar.com/copay](https://acthar.com/copay)

Uninsured/underinsured support

If patients are uninsured or underinsured, they may be able to receive assistance options through the **Acthar Patient Assistance Program**:

- Mallinckrodt provides Acthar Gel at no cost to eligible patients with a valid, on-label prescription for Acthar Gel who have no insurance, are underinsured, or are rendered uninsured
- Their Case Manager will transfer them to the Acthar Patient Assistance Program to determine eligibility
- This program is administered via a third-party organization

Acthar Patient Assistance Program eligibility criteria:

- Valid Acthar Gel prescription for an FDA-approved indication
- Permanent US resident
- Household income at or below 700% of the Federal Poverty Level
- Patients may be subject to random income verification to determine eligibility

Acthar Gel Commercial Co-pay Program Terms and Conditions:

*Terms and Conditions apply. This benefit covers Acthar® Gel (repository corticotropin injection). The program provides up to \$15,000 per calendar year toward the patient's Acthar Gel prescription costs. Eligibility: Available to patients with commercial prescription insurance coverage for Acthar Gel. Co-pay assistance program is not available to patients receiving any form of prescription coverage under any federal, state, or government-funded insurance program or where prohibited by law. Such programs include Medicare (including Medicare Part D and Medicare Advantage), Medigap, Medicaid, TRICARE, Department of Defense, or Veterans Affairs programs. If at any time a patient begins receiving prescription drug coverage under any such federal, state, or government-funded healthcare program, patient will no longer be able to use the Acthar Gel Copay Card and patient must call Acthar Patient Support at 1-888-435-2284 to stop participation. The value of this program is exclusively for the benefit of patients and is intended to be credited towards patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. Patients are responsible for any out-of-pocket costs above and beyond the program's annual maximum benefit. The offer does not constitute prescription drug coverage and is not intended to substitute health insurance. Patients who are members of insurance plans that adjust their patients' out of pocket co-pay or co-insurance responsibilities for certain prescription drugs based upon the patient's enrollment in manufacturer sponsored co-pay assistance for such drugs (often termed "accumulator" or "maximizer" programs) may be restricted from the Acthar Gel Copay Card program. Patients may not seek reimbursement for value received from the Acthar Gel Copay program from any third-party payers. Restrictions, including monthly maximums, may apply. Other Terms and Conditions apply. Offer subject to change or discontinuance without notice.

SELECT IMPORTANT SAFETY INFORMATION

Pregnancy

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

Acthar® Gel Commercial Starter Program

For eligible patients[†] who are awaiting insurance approval for Acthar Gel, jump-start their treatment on Acthar for **free** while they await the outcome of their reimbursement process.



See if your patients are eligible for this program

To be eligible for the commercial starter program, patients must have:

1. A valid prescription for an on-label indication
2. **Not** used Acthar Gel any time in the past 36 months
3. Commercial or private insurance



Help your appropriate patients get Acthar Gel

Patients who have commercial or private insurance can get Acthar Gel promptly. McKesson Specialty Pharmacy will arrange delivery of Acthar Gel directly with the approved patient, 1 vial at a time, as long as it is prescribed to them or until their reimbursement process is completed.



Continue your patient's treatment when the reimbursement process is completed

- If coverage is approved, the patient will receive Acthar Gel vials through their own Specialty Pharmacy with coverage by their insurance provider
- If coverage is denied, the patient will then be screened for eligibility to the Acthar Patient Assistance Program
- When the reimbursement process is completed, the patient will no longer receive Acthar Gel vials under this program

See full program Terms and Conditions below.

Complete the Acthar Gel Commercial Starter Program enrollment in section 5 of the Referral Form and make sure you have appropriate signatures before submitting the form to the Acthar Patient Services HUB.

†Acthar Gel Commercial Starter Program Terms and Conditions:

Eligible patients for this Program must meet the following criteria: have a valid prescription for selected on-label indication in the therapeutic area of rheumatology, pulmonology, ophthalmology, or nephrology, have not used Acthar Gel (currently or in the past 36 months), 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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Patient Support

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 full [Prescribing Information](#) for additional Important Safety Information.

References: 1. Acthar Gel (repository corticotropin injection) [prescribing information]. Bedminster, NJ: Mallinckrodt ARD LLC. 2. Fleischmann R, Furst DE, Connolly-Strong E, Liu J, Zhu J, Brasington R. Repository corticotropin injection for active rheumatoid arthritis despite aggressive treatment: a randomized controlled withdrawal trial. *Rheumatol Ther*. 2020;7(2):327-344. 3. Aggarwal R, Marder G, Koontz DC, Nandkumar P, Qi Z, Oddis CV. Efficacy and safety of adrenocorticotrophic hormone gel in refractory dermatomyositis and polymyositis. *Ann Rheum Dis*. 2018;77(5):720-727. 4. Baughman RP, Barney JB, O'Hare L, Lower EE. A retrospective pilot study examining the use of Acthar gel in sarcoidosis patients. *Respir Med*. 2016;110:66-72. 5. Hladunewich MA, Cattran D, Beck LH, et al. A pilot study to determine the dose and effectiveness of adrenocorticotrophic hormone (Acthar® Gel) in nephrotic syndrome due to idiopathic membranous nephropathy. *Nephrol Dial Transplant*. 2014;29(8):1570-1577. 6. Bomback AS, Canetta PA, Beck LH Jr, Ayalon R, Radhakrishnan J, Appel GB. Treatment of resistant glomerular diseases with adrenocorticotrophic hormone gel: a prospective trial. *Am J Nephrol*. 2012;36(1):58-67. 7. Madan A, Mijovic-Das S, Stankovic A, Teehan G, Milward AS, Khastgir A. Acthar gel in the treatment of nephrotic syndrome: a multicenter retrospective case series. *BMC Nephrol*. 2016;17:37. 8. Tumlin J, Galphin C, Santos R, Rovin B. *Kidney Int Rep*. 2017;2(5):924-932. 9. Bomback AS, Tumlin JA, Baranski J, et al. Treatment of nephrotic syndrome with adrenocorticotrophic hormone (ACTH) gel. *Drug Des Devel Ther*. 2011;5:147-153. 10. Filippone EJ, Dopson SJ, Rivers DM, et al. Adrenocorticotrophic hormone analog use for podocytopathies. *Int Med Case Rep J*. 2016;9:125-133. 11. Hogan J, Bomback AS, Mehta K, et al. Treatment of idiopathic FSGS with adrenocorticotrophic hormone gel. *Clin J Am Soc Nephrol*. 2013;8(12):2072-2081. 12. Wirta D, McLaurin E, Ousler G, Liu J, Kacmaz RO, Grieco J. Repository corticotropin injection (Acthar® Gel) for refractory severe noninfectious keratitis: efficacy and safety from a phase 4, multicenter, open-label study. *Ophthalmol Ther*. 2021;10(4):1077-1092.

Questions?

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Acthar GEL
(repository corticotropin injection) 80 U/mL

Patient Support



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

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