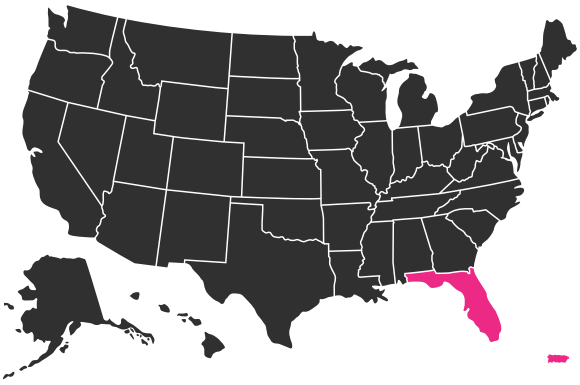
# FCSO Medicare Administration Contractor (MAC) Coding for Purified Cortrophin® Gel When Administered by a Healthcare Provider in an Outpatient Setting

Purified Cortrophin® Gel
repository corticotropin injection USP 80 U/mL

## Disclaimer

Please note this information is intended for informational purposes only and does not guarantee coverage or reimbursement or provide legal advice. This resource is not intended to increase or maximize reimbursement by any payer. While ANI has attempted to be current as of the issue date, this information may not reflect current policies. **It is the HCP's responsibility to confirm coverage, coding, and billing requirements with the patient's individual payer.** Coding and coverage policies are subject to change.



| FCSO | | |
|---|---|---|
| **Medicare** | **JN** | Providers in FL & Puerto Rico |
| **FCSO contact information** | **JN** | 1-877-847-4992 MON-FRI 8 AM - 4 PM ET/CT or Secure Provider Online Tool (SPOT) |

## SELECT INDICATIONS

Cortrophin Gel is a prescription medicine that is injected subcutaneously or intramuscularly. It is indicated for:

- Short-term administration as an adjunctive therapy during an acute episode or exacerbation in rheumatoid arthritis, including juvenile rheumatoid arthritis; psoriatic arthritis; ankylosing spondylitis; and acute gouty arthritis.
- Severe acute and chronic allergic and inflammatory conditions affecting the eye and its adnexa, such as allergic conjunctivitis, keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, and anterior segment inflammation.
- Acute exacerbations of multiple sclerosis.

## IMPORTANT SAFETY INFORMATION

### Contraindications

- Cortrophin Gel is contraindicated for intravenous administration.
- Cortrophin Gel is contraindicated in patients who have any of the following conditions: scleroderma; osteoporosis; systemic fungal infections; ocular herpes simplex; recent surgery; history of or the presence of a peptic ulcer; congestive heart failure; hypertension; primary adrenocortical insufficiency; adrenocortical hyperfunction; or sensitivity to proteins derived from porcine sources.

## Coding Information for Purified Cortrophin® Gel

| Code Set | Code | Description |
|---|---|---|
| **HCPCS**[1] | J0802 | Injection, corticotropin (ani), up to 40 units |
| **Modifier**[a] | JB | Administered subcutaneously |
| | No modifier | Administered intramuscularly |
| **NDC**[2] | 62559-0860-11 | 1 mL multiple-dose vial containing 80 USP units/mL |
| **CPT**[3] | 96372 | Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular |
| **ICD-10-CM** | Varies by indication. Consult your ICD-10-CM reference for a complete list of codes , available at https://cortrophin.com/pdfs/purified-cortrophin-gel-icd-10-diagnosis-codes.pdf | |

[a]Please see PI (or a Medicare compendia, such as DRUGDEX®) for specific information on routes of administration by indication.

### FCSO Claim Submission Guidance[4] as of 06/01/2025. For the most up-to-date information, contact your MAC directly.

According to FCSO, "the use of the JA and JB modifiers is required for drugs which have one HCPCS Level II (J or Q) code but multiple routes of administration. Drugs that fall under this category will be marked with an asterisk (*) and must be billed with the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous form of administration. Absent evidence to the contrary, the Contractor presumes that drugs delivered intravenously are not usually self-administered by the patient. The Contractor will process claims with the JA modifier still applying the policy as stated in the Medicare Benefit Policy Manual, Chapter 15, Section 50.2 that not only must the drug be medically reasonable and necessary, but also that the route of administration is medically reasonable and necessary. Subcutaneously administered drugs listed on the Usually Self-Administered list will be denied as a benefit exclusion. Claims for drugs marked with an asterisk (*) billed without either a JA or JB modifier will also be denied."

However, according to FCSO, Cortrophin Gel, represented by HCPCS code J0802, is administered by IM or SQ; therefore, it "requires the JB modifier to be reported for SQ administration and [it] should not have any modifier reported for the IM administration."

For complete context, refer to the FCSO Self-Administered Drug Exclusion List. For specific questions, please contact your MAC. For additional coding information, see a 1-mL Vial Billing and Coding Guide or the Letter of Appeal template provided by the 1-mL *Cortrophin In Your Corner* reimbursement specialist by calling 1-888-249-2669.

# IMPORTANT SAFETY INFORMATION (cont.)

## Warnings and Precautions

- **Infections:** Corticotropin therapy may increase susceptibility to infections and may mask the symptoms of infections.
- **Adrenal insufficiency:** Prolonged corticotropin therapy can increase the potential for adrenal insufficiency after withdrawal of the medication. Adrenal insufficiency may be minimized by gradually reducing the corticotropin dosage. Hormone therapy should be reinstituted if stressful situations arise during discontinuation.

# IMPORTANT SAFETY INFORMATION (cont.)

## Warnings and Precautions (cont.)

- **Elevated blood pressure, salt and water retention, and hypokalemia:** Corticotropin can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium or calcium.
- **Masking symptoms of other diseases:** Corticotropin may only suppress signs and symptoms of chronic disease without altering the natural course of disease.
- **Psychiatric reactions:** Psychic derangements may appear when corticotropin is used, ranging from euphoria, insomnia, mood swings, personality changes, and depression to psychosis. Existing conditions may be aggravated.
- **Ophthalmic reactions:** Prolonged use of corticotropin may produce posterior subcapsular cataracts and glaucoma with possible damage to the optic nerves.
- **Immunogenicity potential:** Prolonged administration of Cortrophin Gel 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 Cortrophin Gel activity.
- **Vaccination:** Patients should not be vaccinated against smallpox while on corticotropin therapy. Other immunizations should be undertaken with caution due to possible neurologic complications and lack of antibody response.
- **Use in patients with hypothyroidism and cirrhosis:** There is an enhanced effect in patients with hypothyroidism and in those with cirrhosis.
- **Use in patients with latent tuberculosis or tuberculin reactivity:** Closely observe for reactivation of the disease.
- **Comorbid diseases:** Corticotropin should be used with caution in patients with diabetes, abscess, pyogenic infections, diverticulitis, renal insufficiency, and myasthenia gravis.
- **Growth and development:** Carefully observe growth and development of infants and children on prolonged corticotropin therapy.
- **Acute gouty arthritis:** Treatment of acute gouty arthritis should be limited to a few days. Conventional concomitant therapy should be administered during corticotropin treatment and for several days after it is stopped.
- **Drug interactions:** Aspirin should be used cautiously with corticotropin in hypoprothrombinemia.
- **Pregnancy:** Since fetal abnormalities have been observed in animals, Cortrophin Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

## Adverse Reactions

Adverse reactions for Cortrophin Gel include fluid or sodium retention; muscle weakness; osteoporosis; peptic ulcer with possible perforation and hemorrhage; injection site reactions; impaired wound healing; hypertension; convulsions; headache; development of Cushingoid state; suppression of growth in children; anaphylaxis (anaphylactic shock, urticaria, respiratory compromise, edema); and weight gain. These are not all the adverse reactions reported with Cortrophin Gel.

## References


1. CMS. January 2024 alpha-numeric HCPCS file. Accessed February 2, 2024. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update
2. Purified Cortrophin Gel. Prescribing information. ANI Pharmaceuticals, Inc.
3. American Medical Association. 2024 CPT Professional Edition. AMA; 2023.
4. First Coast Service Options, Inc. Self-Administered Drug Exclusion List. Revised June 1, 2025. Accessed July 29, 2025. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52571&ver=106&keyword=&keywordType=starts&areaId=all&docType=6,3,5,1,F,P&contractOption=all&hcpcsOption=code&hcpcsStartCode=j0802&hcpcsEndCode=j0802&sortBy=title&bc=1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