BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.30.080

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	January 21, 2022
Subject:	Cortrophin Gel	**Page:**	1 of 6

Last Review Date: March 8, 2024

Cortrophin Gel

Description

Cortrophin Gel (corticotropin injection; ACTH)

Background
Purified Cortrophin Gel is a porcine derived purified corticotropin (ACTH) in a sterile solution of gelatin. It is made up of a complex mixture of ACTH, ACTH related peptides, and other porcine pituitary derived peptides. Purified Cortrophin Gel is the anterior pituitary hormone which stimulates the functioning adrenal cortex to produce and secrete adrenocortical hormones (1).

Regulatory Status
FDA-approved indications: Cortrophin Gel is indicated in the following disorders: (1)

1. Rheumatic disorders:
    a. As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:
        i. Psoriatic arthritis
        ii. Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)
        iii. Ankylosing spondylitis
        iv. Acute gouty arthritis
2. Collagen diseases:
    a. During an exacerbation or as maintenance therapy in selected cases of:
        i. Systemic lupus erythematosus
        ii. Systemic dermatomyositis (polymyositis)
3. Dermatologic diseases:
    a. Severe erythema multiforme (Stevens-Johnson syndrome)

   b. Severe psoriasis
4. Allergic states:
   a. Atopic dermatitis
   b. Serum sickness
5. Ophthalmic diseases:
   a. Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as:
      i. Allergic conjunctivitis
      ii. Keratitis
      iii. Iritis and iridocyclitis
      iv. Diffuse posterior uveitis and choroiditis
      v. Optic neuritis
      vi. Chorioretinitis
      vii. Anterior segment inflammation
6. Respiratory diseases:
   a. Symptomatic sarcoidosis
7. Edematous states:
   a. To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus
8. Nervous system:
   a. Acute exacerbations of multiple sclerosis

Cortrophin Gel is contraindicated for intravenous administration (1).

Cortrophin Gel 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, hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, or sensitivity to proteins derived from porcine sources (1).

Related policies
Acthar Gel

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Cortrophin Gel may be considered **medically necessary** if the conditions indicated below are met.

Cortrophin Gel may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Rheumatic disorder:
    a. Psoriatic arthritis
    b. Rheumatoid arthritis, including juvenile rheumatoid arthritis
    c. Ankylosing spondylitis
    d. Acute gouty arthritis
2. Collagen disease:
    a. Systemic lupus erythematosus
    b. Systemic dermatomyositis (polymyositis)
3. Dermatologic disease:
    a. Severe erythema multiforme (Stevens-Johnson syndrome)
    b. Severe psoriasis
4. Allergic state:
    a. Atopic dermatitis
    b. Serum sickness
5. Ophthalmic disease:
    a. Allergic conjunctivitis
    b. Keratitis
    c. Iritis and iridocyclitis
    d. Diffuse posterior uveitis and choroiditis
    e. Optic neuritis
    f. Chorioretinitis
    g. Anterior segment inflammation
6. Respiratory disease:
    a. Symptomatic sarcoidosis
7. Nephrotic syndrome
    a. Prescribed by a nephrologist
    b. Patient has had an inadequate treatment response or intolerance to a 1 month trial of **ONE** of the following:

i. Oral glucocorticoid therapy
ii. Immunosuppressant such as:
1. Cyclophosphamide
2. Cyclosporine
3. Tacrolimus
4. Mycophenolate mofetil

c. Patient has baseline levels of protein in urine indicative of proteinuria and low levels of albumin in blood indicative of hypoalbuminemia

8. Exacerbations of multiple sclerosis (MS)
a. Prescribed by a neurologist
b. Used in combination with a maintenance MS therapy
c. Patient has **ONE** of the following:
i. FDA labeled contraindication to oral or parenteral glucocorticoid therapy
ii. An inadequate response or intolerance to a 1 month trial of oral or a 1 week trial of parenteral glucocorticoid therapy

AND the following for **ALL** indications:
1. **NO** dual therapy with Acthar Gel (corticotropin)

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Rheumatic disorder:
a. Psoriatic arthritis
b. Rheumatoid arthritis, including juvenile rheumatoid arthritis
c. Ankylosing spondylitis
d. Acute gouty arthritis
2. Collagen disease:
a. Systemic lupus erythematosus
b. Systemic dermatomyositis (polymyositis)
3. Dermatologic disease:
a. Severe erythema multiforme (Stevens-Johnson syndrome)
b. Severe psoriasis
4. Allergic state:

   a. Atopic dermatitis
   b. Serum sickness
5. Ophthalmic disease:
   a. Allergic conjunctivitis
   b. Keratitis
   c. Iritis and iridocyclitis
   d. Diffuse posterior uveitis and choroiditis
   e. Optic neuritis
   f. Chorioretinitis
   g. Anterior segment inflammation
6. Respiratory disease:
   a. Symptomatic sarcoidosis
7. Nephrotic syndrome
   a. Prescribed by a nephrologist
   b. Patient has had a decrease in urine protein level and an increase in serum albumin level
8. Exacerbations of multiple sclerosis (MS)
   a. Prescribed by a neurologist
   b. Used in combination with a maintenance MS therapy
   c. Patient has had a 30 day lapse since previous exacerbation

AND the following for **ALL** indications:

1. **NO** dual therapy with Acthar Gel (corticotropin)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration	Exacerbations of multiple sclerosis	1 month
	Nephrotic syndrome	6 months
	All other indications	12 months

Prior – Approval *Renewal* Limits

Same as above

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Rationale

Summary
Cortrophin Gel stimulates the release of andrenocortical hormones. It is approved for several indications that are more generally treated with corticosteroids, such as rheumatoid arthritis, systemic lupus erythematosus, severe psoriasis, etc. (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Cortrophin Gel while maintaining optimal therapeutic outcomes.

References

1. Cortrophin Gel [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc.; October 2023.

Policy History

Date	Action
January 2022	Addition to PA
March 2022	Annual review
April 2022	Per FEP, addition of no dual therapy with Acthar Gel and removed Cortrophin Gel from managed PA
June 2022	Annual review
March 2023	Annual review and reference update. Changed policy number to 5.30.080
September 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.