



Care1st Health Plan Arizona, Inc.

Easy Choice Health Plan

Harmony Health Plan of Illinois

Missouri Care

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona

OneCare (Care1st Health Plan Arizona, Inc.)

Staywell of Florida

WellCare (Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Prescription Insurance

Repository Corticotropin Injection (HP Acthar Gel)

Policy Number: HS-306

Original Effective Date: 10/17/2015

Revised Date(s): 10/6/2016; 8/3/2017

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any. All links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change prior to the annual review date. Lines of business (LOB) are subject to change without notice; current LOBs can be found at www.wellcare.com. All guidelines can be found at this site as well but selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

HP Acthar Gel is an adrenocorticotrophic hormone (ACTH) analogue indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. HP Acthar Gel is also indicated for the treatment of exacerbations of multiple sclerosis in adults. HP Acthar Gel may be used for the following disorders and diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state.¹

POSITION STATEMENT

Applicable To:

- Medicaid
- Medicare

Exclusions

HP Acthar Gel is unproven and not medically necessary as a first-line therapy in these conditions as treatment with HP Acthar is not well established for the following:

- Rheumatic Disorders: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis, ankylosing spondylitis
- Collagen Diseases: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
- For diagnostic testing of adrenocortical function because it has not been shown to be superior to cosyntropin for this purpose.
- For corticosteroid-responsive conditions because it has not been proven to be more effective than corticosteroids for these indications.
- For all other indications including the following (not an all-inclusive list) because its effectiveness for these indications has not been established:
 - Dermatopolymyositis
 - Nephrotic syndrome (including focal segmental glomerulo-sclerosis, idiopathic membranous nephropathy, IgA nephropathy, membrano-proliferative glomerulo-nephritis, and monoclonal diffuse proliferative glomerulo-nephritis)
 - Systemic lupus erythematosus

HP Acthar gel is contraindicated in the following situations:

- For use via intravenous administration.
- In suspected congenital infections in infants.
- Administration of live or live attenuated vaccines in members receiving immunosuppressive doses of HP Acthar gel.
- For individuals with: scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, CHF, uncontrolled hypertension, primary adrenocortical insufficiency, and adrenocortical hyperfunction or sensitivity to proteins of porcine origin.

Coverage

Repository corticotropin (HP Acthar® Gel) **is considered medically necessary** when one of the following is met:

- **For the treatment of West syndrome** (infantile spasms) in infants and children less than two years of age. Repository corticotropin injection dosing for infantile spasm is as follows:
 - Initial dose: 75 U/m² intramuscular (IM) twice daily for 2 weeks.
 - After 2 weeks, dose should be tapered according to the following schedule: 30 U/m² IM in the morning for 3 days; 15 U/m² IM in the morning for 3 days; 10 U/m² IM in the morning for 3 days; and 10 U/m² IM every other morning for 6 days (3 doses).
 - BSA (m²): $\sqrt{\frac{weight (kg) \times height (cm)}{3600}}$
 - Additionally, baseline 24 hour EEG displaying hysarrythmia must be made available.

NOTE: Additional information to support medical necessity review where applicable: The above indication and criteria also apply to medical necessity review.

OR

- **For the treatment of multiple sclerosis** in adult members 18 years or older:
 - Member is an adult with a corticosteroid-responsive condition, including but not limited to acute exacerbations of multiple sclerosis; **AND**
 - There is denotation of an acute exacerbation lasting at least 24 hours; **AND**
 - Other exacerbation causes such as stress, pain, or infection have been ruled out; **AND**
 - Member has no contraindications to or is not limited by contraindication to or intolerance of glucocorticoid effects; **AND**
 - Immunomodulator use for at least the past 30 days (such as Aubagio, Avonex, Copaxone, Betaseron, Rebif, Gilenya, and Tysabril); **AND**
 - Documented trial & failure of methylprednisolone 160mg daily for one week followed by 64mg every other day for one month; **AND**
 - There is clear documentation of why all other well-established routes for corticosteroid therapy (for example, oral prednisone and intravenous methylprednisolone) cannot be used.
 - Documentation of taper schedule; **AND**
 - Recommended dosing for the treatment of acute exacerbations of multiple sclerosis in adults is 80 – 120 units injected intramuscularly or subcutaneously daily for 2-3 week.

OR

- ***** For the treatment of nephrotic syndrome** in adult member 18 years and older:
 - Must have trial and failure or intolerance of at least 1 from the following categories (unless adequate documentation reflects contraindication):
 - Immunosuppressive agents: cyclophosphamide, mycophenolate mofetil, tacrolimus or cyclosporine; **AND/OR**
 - Corticosteroid (Prednisolone, Dexamethasone IV); **AND/OR**
 - Methylprednisolone IM injection.

OR

- ***** For the treatment of polymyositis/dermatomyositis** in adults 18 years or older:
 - Must have trial and failure or intolerance of at least 1 from each of the following groups (unless adequate documentation reflects contraindication):
 - Corticosteroid (Prednisolone, Dexamethasone IV); **AND**
 - Antimetabolite (azathioprine, methotrexate); **AND**
 - Methylprednisolone IV.

OR

- ***** For the treatment of Rheumatoid Arthritis** in adult members 18 years and older:
 - Must have trial and failure or intolerance of at least 1 from each of the following groups (unless adequate documentation reflects contraindication):
 - Corticosteroid (Prednisolone, Dexamethasone IV); **AND/OR**
 - Antirheumatic (azathioprine, methotrexate, Humira, Enbrel); **AND/OR**
 - Methylprednisolone IM injection between 40 to 120mg or IV.

OR

- **For the treatment of Systemic Lupus Erythematosus** in adults 18 years and older:
 - Must have trial and failure or intolerance of at least 1 from each of the following groups (unless adequate documentation reflects contraindication):
 - Corticosteroid (Prednisolone, Dexamethasone IV); **AND/OR**
 - Hydroxychloroquine, Benlysta, azathioprine, cyclosporine, cyclophosphamide, mycophenolate; **AND/OR**
 - Methylprednisolone IV

OR

- **For the treatment of Sarcoidosis** in adults 18 years and older:
 - Must have trial and failure or intolerance of at least 1 from each of the following groups (unless adequate documentation reflects contraindication)
 - Corticosteroid (IV methylprednisolone, IV dexamethasone, oral prednisone); **AND/OR**
 - Immunosuppressant (methotrexate, azathioprine); **AND/OR**

*** These as well as certain collagen diseases, allergic states, ophthalmic diseases, are labeled indications however; HP Acthar is not first-line in these conditions as treatment with HP Acthar is not well established. .

CODING

Covered CPT Code

96372 Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

Covered HCPCS Code

J0800 Injection, corticotropin, up to 40 units

Covered ICD-10-CM Diagnosis Codes

D86.0-D86.9	Sarcoidosis
G35	Multiple sclerosis
G40.821 - G40.824	Epileptic spasms [West's syndrome]
L40.54	Psoriatic juvenile arthropathy
M05.00-M05.9	Rheumatoid arthritis with rheumatoid factor
M06.00-M06.09	Rheumatoid arthritis without rheumatoid factor
M06.80-M06.89	Other specified rheumatoid arthritis
M06.9	Rheumatoid arthritis, unspecified
M08.00-M08.09	Unspecified juvenile rheumatoid arthritis
M08.1	Juvenile ankylosing spondylitis
M08.20-M08.29	Juvenile rheumatoid arthritis with systemic onset
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M08.40-M08.48	Pauciarticular juvenile rheumatoid arthritis
M32.0-M32.9	Systemic lupus erythematosus
M33.00-M33.99	Dermatopolymyositis
M45.0-M45.9	Ankylosing spondylitis
N04.0-N04.9	Nephrotic syndrome

*Current Procedural Terminology (CPT®) 2015 American Medical Association: Chicago, IL.

REFERENCES

1. Prescribing information. Mallinckrodt Web site. <http://www.acthar.com/>. Accessed July 12, 2017.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
8/3/2017, 8/3/2016, 10/6/2016 10/17/2015	<ul style="list-style-type: none"> • Approved by MPC. No Changes. • Approved by MPC. New.