POLICY

A. COVERED INDICATIONS
H.P. Acthar Gel is covered (subject to Criteria for Approval and Exclusions) as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.

B. CRITERIA FOR INITIAL APPROVAL
Infantile Spasms
- Authorization of 6 months may be granted to members less than 2 years of age diagnosed with infantile spasms.

C. CRITERIA FOR CONTINUATION OF THERAPY
1. No previous authorization/precertification:
   All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section B.
2. Reauthorization:
   Authorization of an additional 6 months may be granted to members requesting authorization for continuation of therapy who are benefiting from H. P. Acthar Gel therapy for infantile spasms if substantial clinical benefit from therapy has been shown and were previously authorized by HMSA/CVS.

D. EXCLUSIONS
H.P. Acthar Gel is not covered for any other indication, including but not limited to:
- Acute exacerbation of multiple sclerosis
- Rheumatic disorders (eg, psoriatic arthritis, rheumatoid arthritis)
- Collagen diseases (eg, systemic lupus erythematosus, dermatomyositis)
- Dermatologic diseases
- Allergic states (eg, serum sickness)
- Ophthalmic diseases
- Respiratory diseases (eg, sarcoidosis)
- Edematous states (eg, nephrotic syndrome)

E. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.
F. IMPORTANT REMINDER

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA/CVS determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

G. REFERENCES