## Repository Corticotropin Injection (H.P. Acthar Gel, Purified Cortrophin Gel)

Override(s)	Approval Duration
Prior Authorization	3 months

Medications	
H.P. Acthar Gel	
(repository corticotropin injection)	
Purified Cortrophin Gel	
(repository corticotropin injection)	

## **APPROVAL CRITERIA**

Requests for repository corticotropin injection (H.P. Acthar Gel or Purified Cortrophin Gel) may be approved if the following criterion is met:

I. Individual is an infant or child less than 2 years of age and is using as monotherapy for the treatment of infantile spasms (West syndrome).

Repository corticotropin injection (H.P. Acthar Gel, Purified Cortrophin Gel) may not be approved when the above criteria are not met and for all other indications.

## **Kev References**:

- Abbruzzese G, Gandolfo C, Loeb C. "Bolus" methylprednisolone versus ACTH in the treatment of multiple sclerosis. Ital J Neurol Sci. 1983; 4(2):169-172.
- 2. Baram TZ, Mitchell WG, Tournay A, et al. High-dose corticotropin (ACTH) versus prednisone for infantile spasms: a prospective, randomized, blinded study. *Pediatrics*. 1996; 97(3):375-379.
- 3. Baughman RP, Sweiss N, Keijsers R, et al. Repository corticotropin for chronic pulmonary sarcoidosis. Lung. 2017; 195(3):313-322.
- 4. Bomback AS, Tumlin JA, Baranski J, et al. Treatment of nephrotic syndrome with adrenocorticotropic hormone (ACTH) gel. *Drug Des Devel Ther.* 2011; 5:147-153
- 5. Chen Y, Schieppati A, Cai G, et al. Immunosuppression for membranous nephropathy: a systematic review and metaanalysis of 36 clinical trials. *Clin J Am Soc Nephrol*. 2013; 8(5):787-796.
- 6. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 24, 2021.
- 7. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 8. Fiechtner J, Montroy T. Treatment of moderately to severely active systemic lupus erythematosus with adrenocorticotropic hormone: a single-site, open-label trial. *Lupus*. 2014; 23(9):905-912.

- 9. Filippini G, Brusaferri F, Sibley WA, et al. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. Cochrane Database Syst Rev. 2000;(4):CD001331.
- 10. Glaze DJ. Management and prognosis of infantile spasms. Last updated: July 27, 2021. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 31, 2021.
- Go CY, Mackay MT, Weiss SK, et al. Evidence-based guideline update: Medical treatment of infantile spasms. Report of the Guideline Development Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. Neurology. 2012; 78(24):1974-1980.
- 12. Hladunewich MA, Cattran D, Beck LH, et al. A pilot study to determine the dose and effectiveness of adrenocorticotrophic hormone (H.P Acthar<sup>(R)</sup> Gel) in nephrotic syndrome due to idiopathic membranous nephropathy. *Nephrol Dial Transplant*. 2014; 29(8):1570-1577.
- 13. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
- 14. Madan A, Mijovic-Das S, Stankovic A, et al. Acthar gel in the treatment of nephrotic syndrome: a multicenter retrospective case series. *BMC Nephrol*. 2016; 17:37.
- 15. Miller H, Newell DJ, Ridley A. Multiple sclerosis. Treatment of acute exacerbations with corticotrophin (A.C.T.H.). *Lancet*. 1961; 2(7212):1120-1122.
- 16. Olek MJ, Howard J. Treatment of acute exacerbations of multiple sclerosis in adults. Last updated: March 4, 2021. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 31, 2021.
- 17. Rose AS, Kuzma JW, Kurtzke JF, et al. Cooperative study in the evaluation of therapy in multiple sclerosis. ACTH vs. placebo--final report. *Neurology*. 1970; 20(5):1-59.
- 18. Thompson AJ, Kennard C, Swash M, et al. Relative efficacy of intravenous methylprednisolone and ACTH in the treatment of acute relapse in MS. *Neurology*. 1989; 39(7):969-971.
- 19. Watson MJ. Membranous glomerulopathy and treatment with Acthar®: a case study. *Int J Nephrol Renovasc Dis.* 2013; 6:229-232.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.