Drug Name: H.P. Acthar Gel (repository corticotropin)
Date: 9-2017

Drug Name:	H.P. Acthar Gel (repository corticotropin)
Prescriber Restrictions:	
Age Restrictions:	Dependent on indication
Exclusion Criteria:	*H.P. Acthar is not approvable in patients with any contraindications to the drug such as: hypersensitivity to proteins of porcine origin, scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, peptic ulcer, recent surgery, congestive heart failure (CHF), uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, infants with suspected congenital infections, coadministration of live or live attenuated vaccines, I.V. administration.*
Required Medical Information:	*Infantile Spasm* • Patient is less than 24 months old and being treated for infantile spasms and • Patient has failed course of IV corticosteroid (in the active form; e.g. methylprednisolone); and • Patient is receiving a dose of up to 150 U/m^2/day in divided doses and • Patient is being treated for H.P. Acthar for no more than 4 weeks in duration. H.P. Acthar is not intended for prolonged use due to risk of hypothalamic-pituitary-axis suppression; cushings syndrome; and impact on growth (e.g. bone) development *Opsoclonus Myoclonus* • Patient is less than 5 years old and being treated for opsoclonus myoclonus and • Patient is being treated with concurrent IV immunoglobulin and at least one other agent; and • H.P. Acthar dose will not exceed 150 units per day *Multiple Sclerosis* • Patient is diagnosed with multiple sclerosis exacerbation and • Patient has failed IV Methylprednisolone therapy; and • H.P. Acthar dose will not exceed 120 units daily; and • Patient will be treated with H.P. Acthar for no more than 3 weeks in duration *Nephrotic Syndrome* • Patient has primary focal glomerulosclerosis or membranous nephropathy proven by renal biopsy • Is under the care of a nephrologist. • Patient has active nephrotic syndrome (characterized by proteinuria > 4 Uprot/Ucr), which does not respond to immunosuppressive

	treatment.
	• Patients has failed first line glucocorticoid trial (prednisone for 8-16 weeks) and
	• Patient has failed a trial of alternative immune-suppressive agents (e.g. cyclophosphosphomide, tacrolimus, or cyclosporine) and be deemed steroid dependent or steroid resistant.
	  o Steroid dependent is defined as patients who relapse during glucocorticoid taper, or within two months after cessation of glucocorticoid treatment
	  o Steroid resistance is defined as patients who never achieved remission while on glucocorticoid therapy.
	• Approved for three months. Greater than 3 months, prescriber will need to provide clinical rational for continuing (ex. no response at lower dose of 40U twice weekly or similar)
	  o If no effect after three months, consider discontinuing. Therapeutic effect includes improvement in proteinuria with >50% decrease, improvement in serum albumin, lipid panel improvement. Therapeutic failure if worsening proteinuria or failure to reach 50% reduction in proteinuria inadequate response and/or intolerance
	
	Other Indications
	• Patient is being treated short-term for an indication not provided above for which H.P. Acthar Gel is indicated (e.g. exacerbation of rheumatoid arthritis); and
	• Patient has failed an adequate dose and duration of at least two other conventional therapies indicated in therapy for treating diagnosis; and
	• Patient has failed an adequate dose and duration of corticosteroid therapy; and
	• Patient will be treated with H.P. Acthar for no more than 3 weeks.