SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Repository Corticotropin Medications
Systemic Lupus Erythematosus (SLE)

PREFERRED	NON-PREFERRED
❑ **Purified Cortrophin™ Gel** (repository corticotropin)	❑ **Acthar® Gel** (repository corticotropin) 80 USP Units/mL 5 mL multi-dose vial ❑ **Acthar® Gel** (repository corticotropin) 40 USP Units/0.5 mL single-dose prefilled SelfJect injector ❑ **Acthar® Gel** (repository corticotropin) 80 USP Units/mL single-dose prefilled SelfJect injector ***Member must have tried and failed preferred Purified Cortrophin™ Gel and meet all applicable PA criteria below**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

- Repository corticotropin is a form of adrenocorticotropic hormone (ACTH). It works by stimulating the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a few other weakly androgenic substances. Repository corticotropin has been compared in studies with other therapeutically equivalent alternatives such as cosyntropin and corticosteroids.

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- There is a lack of controlled studies for Nephrotic Syndrome that has hindered development of guidelines on treatment. The Kidney International Supplements (2012) and other clinical practice guidelines were used for this prior authorization form.
- Adverse effects that may occur with repository corticotropin are related primarily to its **steroidogenic effects and are similar to corticosteroids**. There may be increased susceptibility to new infection and increased risk of reactivation of latent infections. Adrenal insufficiency may occur after abrupt withdrawal of the drug following prolonged therapy.
- Acthar Gel single-dose pre-filled SelfJect injector is for subcutaneous administration by adults only.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Use of repository corticotropin injection is not considered medically necessary as treatment of corticosteroid responsive conditions

- ❑ Member must have had concurrent flares of inflammation of the joints and/or recurrence or new rash formation while on high dose steroids in combination with immunosuppressant therapy
- ❑ Does the member have any of the following contraindications to Repository Corticotropin Therapy? (Check all that apply. If none, check "none of the above." Requested medication will not be approved if member has any of the following contraindications)

❑ Scleroderma	❑ Osteoporosis	❑ Systemic fungal infection
❑ Ocular herpes simplex	❑ Congestive heart failure	❑ Uncontrolled hypertension
❑ Primary adrenocortical insufficiency	❑ Adrenocortical hyperfunction	❑ Congenital infections (infant)
❑ Primary adrenocortical insufficiency	❑ Known history of a primary immunodeficiency	❑ None of the Above

- ❑ Please note member's current flare symptom(s):

❑ Arthritis (Defined as more than 2 joints with pain and signs of inflammation (i.e. tenderness, swelling, or effusion)
❑ Rash (Defined as new onset or recurrence of inflammatory type rash)
❑ Other: _____ **(must submit current literature to support repository corticotropin effectiveness and primary study endpoint(s) have been met)**

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- ❑ **PAID CLAIMS MUST MATCH STATEMENT BELOW:**

  Member **MUST** have tried and failed the following therapies below for at least 3 months consecutively within the last 12 months. Failure will be defined as no improvement in symptoms while on high dose corticosteroid **(both IV and oral trials required)** and immunosuppressant agent concomitantly. Please note therapies tried:

  - ❑ Prednisone 0.5-1 mg/kg/day IV **AND** Prednisone 0.5-1 mg/kg/day oral **(or an equivalent high dose steroid)**

    Name, dose and dates of the equivalent high does steroid trials: _____

    _____

  - ❑ **PREDNISONE MUST HAVE BEEN TAKEN CONCURRENTLY WITH ONE OF THE FOLLOWING IMMUNOSUPPRESIVE DRUGS FOR AT LEAST 90 DAYS CONSECUTIVELY WITHIN THE LAST 12 MONTHS.** Please note therapy tried **(paid claims WILL be verified through pharmacy records; chart notes documenting failure of prednisone plus concurrent immunosuppressive drug MUST be submitted)**:

❑ Methotrexate (≤ 25 mg/ week)	❑ Azathioprine (TPMT normal) (2-3 mg/kg/day)	❑ Mycophenolic mofetil (2-3 g/day)
❑ Tacrolimus (1-3 mg/day)	❑ Hydroxychloroquine (≤ 6.5 mg/kg/day)	❑ Belimumab (SubQ) (200 mg/week)
❑ Cyclosporine (≤ 2.5 mg/kg/day)	❑ Belimumab (IV) (10 mg/kg/day)	

- ❑ Member must have tried and failed Rituximab therapy at some point within progression of disease.

****NOTE: Approval will be for a period of 8 weeks with a follow up current flare on Arthritis joints or Rash and high dose steroid unresponsiveness must be submitted.**

Medication being provided by a Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****