

SENTARA COMMUNITY PLAN (MEDICAID)

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: Strensiq[®] (asfotase alfa)

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: _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight: _____ Date: _____

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.

For 6 month initial authorization, all of the following criteria must be met

- Member has one of the following diagnoses:
 - Perinatal/infantile-onset hypophosphatasia (HPP)
 - Juvenile-onset hypophosphatasia (HPP)

AND

- Diagnosis was made by or in consultation with a geneticist, metabolic specialist or endocrinologist

AND

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- Member was ≤ 18 years of age at onset of HPP

AND

- Member had low baseline alkaline phosphatase (ALP) activity (age-adjusted) at time of diagnosis and in the absence of bisphosphonate therapy (**age-adjusted lab documenting low ALP level must be submitted**)

AND

- Molecular genetic test has been completed confirming mutations in the ALPL gene that encodes the tissue nonspecific isoenzyme of ALP (TNSALP) (**positive test result must be submitted**)

AND

- Member's diagnosis of HPP was confirmed by the presence of elevated ALP substrate levels [elevated plasma pyridoxal 5'-phosphate (PLP) level and/or elevated urinary phosphoethanolamine (PEA) and/or elevated plasma inorganic pyrophosphate (PPi)] (**diagnostic lab levels must be submitted**)

AND

- Member had at least **ONE** of the following clinical manifestations of HPP with onset prior to age 18 years (**note clinical feature(s) and submit chart notes/lab results/radiographic documentation**):

<input type="checkbox"/> Rachitic chest deformity and/or rib fractures	<input type="checkbox"/> Rickets or infantile rickets	<input type="checkbox"/> Vitamin B6-dependent seizures
<input type="checkbox"/> Respiratory compromise associated with HPP (with or without ventilator support)	<input type="checkbox"/> Short stature, bowed legs or arms, or other skeletal deformity	<input type="checkbox"/> Craniosynostosis associated with HPP
<input type="checkbox"/> Alveolar bone loss	<input type="checkbox"/> Failure to thrive	<input type="checkbox"/> Non-traumatic, poorly-healing fracture(s) associated with HPP
<input type="checkbox"/> Osteopenia, osteoporosis, or low BMD for age	<input type="checkbox"/> Severe muscular hypotonia and weakness associated with HPP	<input type="checkbox"/> Other: _____

AND

- Current weight: _____ and height: _____ (**chart notes documenting current weight and height must be submitted**)
 - Members weighing <40 kg will not be approved for 80mg/0.8mL vial
 - For diagnosis of perinatal/infantile-onset HPP, maximum approved dose will be 9mg/kg/week
 - For diagnosis of juvenile-onset HPP, maximum approved dose will be 6mg/kg/week

AND

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- Baseline ophthalmic exam and renal ultrasound have been performed

For 12 month re-authorization, all of the following criteria must be met

- All initial authorization criteria continues to be met

AND

- Current weight: _____ and height: _____ (**chart notes documenting current weight and height must be submitted**)

AND

- Documentation must be submitted that member has had a clinically significant improvement in bone manifestations or respiratory status with **one** of the following: radiographic evidence of skeletal improvement, pulmonary function tests showing improvement from baseline, and/or improvement in functional ability as evidenced by increased height, strength, growth and motor function

AND

- Ophthalmic exam and renal ultrasound will be performed yearly to monitor for ectopic calcifications of the eyes and kidneys

Medication being provided by Specialty Pharmacy - PropriumRx

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.****