AvMed

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 1-305-671-0200**. 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 AvMed #: _____ **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

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

AND

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- ❑ 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):**

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

- ❑ Baseline ophthalmic exam and renal ultrasound have been performed

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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.****

***Approved by Pharmacy and Therapeutics Committee**: 6/20/2019
REVISED/UPDATED: ~~8/13/2019~~ **10/30/2023**