STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ASFOTASE ALFA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASFOTASE ALFA	STRENSIQ	42649		GPI-10 (3090561000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is this a request for treatment of perinatal/infantile-onset hypophosphatasia (HPP)?

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have a documented diagnosis of perinatal/infantile-onset hypophosphatasia (HPP) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient was 6 months of age or younger at hypophosphatasia (HPP) onset
   - The patient is NOT currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)].
   - The patient is positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing OR meets at least TWO of the following criteria:
     - Serum alkaline phosphatase (ALP) level below that of normal range for patient age
     - Serum pyridoxal-5'-phosphate (PLP) levels elevated AND patient has not received vitamin B_6 supplementation in the previous week
     - Urine phosphoethanolamine (PEA) level above that of normal range for patient age
     - Radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, widened growth plates, areas of radiolucency or sclerosis)
     - Presence of two or more of the following:
       - Rachitic chest deformity
       - Craniosynostosis (premature closure of skull bones)
       - Delay in skeletal growth resulting in delay of motor development
       - History of vitamin B_6 dependent seizures
       - Nephrocalcinosis or history of elevated serum calcium
       - History or presence of non-traumatic postnatal fracture and delayed fracture healing

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is this a request for treatment of juvenile-onset hypophosphatasia (HPP)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a documented diagnosis of juvenile-onset hypophosphatasia (HPP) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient was 18 years of age or younger at hypophosphatasia (HPP) onset
   - The patient is NOT currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)].
   - The patient is positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing OR meets at least TWO of the following criteria:
     - Serum alkaline phosphatase (ALP) level below that of normal range for patient age
     - Serum pyridoxal-5'-phosphate (PLP) levels elevated AND patient has not received vitamin B_6 supplementation in the previous week
     - Urine phosphoethanolamine (PEA) level above that of normal range for patient age
     - Radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, osteomalacia, widened growth plates, areas of radiolucency or sclerosis)
     - Presence of two or more of the following:
       - Rachitic deformities (rachitic chest, bowed legs, knock-knees)
       - Premature loss of primary teeth prior to 5 years of age
       - Delay in skeletal growth resulting in delay of motor development
       - History or presence of non-traumatic fractures or delayed fracture healing

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient meet **ANY** of the following criteria?
   - The patient's serum calcium or phosphate level is below the normal range
   - The patient has a treatable form of rickets

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline

   If no, **approve for 6 months by HICL or GPI-10.**

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ASFOTASE ALFA (Strensiq)** requires the following rules be met for approval:

A. You have a documented diagnosis of perinatal/infantile-onset hypophosphatasia (HPP: a type of genetic condition) or juvenile-onset hypophosphatasia (HPP).
B. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
C. You are NOT currently receiving treatment with a bisphosphonate [such as Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)]
D. **If you have perinatal/infantile-onset hypophosphatasia, approval also requires:**
    1. You were 6 months of age or younger at hypophosphatasia onset
    2. You are positive for a tissue non-specific alkaline phosphatase (a type of enzyme) (ALPL) gene mutation as confirmed by genetic testing OR you meet at least TWO of the following criteria:
        a. Serum alkaline phosphatase (type of enzyme) level below that of normal range for your age
        b. Serum pyridoxal-5'-phosphate (PLP) levels elevated AND you have not received vitamin B6 supplementation in the previous week
        c. Urine phosphoethanolamine (PEA) level above that of normal range for your age
        d. Radiographic evidence of hypophosphatasia [such as flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), widened growth plates, areas of radiolucency (ability to see through with x-rays/ radiation) or sclerosis (hardening of an area)]
        e. Presence of two or more of the following:
            i. Rachitic chest deformity (chest bones are not normal)
            ii. Craniosynostosis (premature closure of skull bones)
            iii. Delay in skeletal growth resulting in delay of motor development
            iv. History of vitamin B6 dependent seizures
            v. Nephrocalcinosis (high calcium levels in kidney) or history of elevated serum calcium
            vi. History or presence of fracture after birth not due to injury or delayed fracture healing

(Initial denial text continued on next page)

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

E. **If you have juvenile-onset hypophosphatasia, approval also requires:**
   1. You were 18 years of age or younger at hypophosphatasia onset
   2. You are positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing OR meet at least TWO of the following criteria:
      a. Serum alkaline phosphatase (type of enzyme) level below that of normal range for your age
      b. Serum pyridoxal-5'-phosphate (PLP) levels elevated AND you have not received vitamin B6 supplementation in the previous week
      c. Urine phosphoethanolamine (PEA) level above that of normal range for your age
      d. Radiographic evidence of hypophosphatasia [such as flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), osteomalacia (bone softening), widened growth plates, areas of radiolucency or sclerosis (hardening of an area)]
      e. Presence of two or more of the following:
         i. Rachitic deformities (rachitic chest, bowed legs, knock-knees)
         ii. Premature loss of primary teeth prior to 5 years of age
         iii. Delay in skeletal growth leading to motor development delay
         iv. History or presence of fracture after birth not due to injury or delayed fracture healing

Strensiq will not be approved if you meet any of the following:

A. Your serum calcium or phosphate level is below the normal range
B. You have a treatable form of rickets (softening and weakening of bones in children, usually due to low vitamin D)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ASFOTASE ALFA

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. During the last 6 months of treatment, has the patient experienced improvement in the skeletal characteristics of hypophosphatasia (HPP) (e.g., improvement of the irregularity of the provisional zone of calcification, physeal widening, metaphyseal flaring, radiolucencies, patchy osteosclerosis, ratio of mid-diaphyseal cortex to bone thickness, gracile bones, bone formation and fractures)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)]?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or by GPI-10.**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ASFOTASE ALFA (Strensiq)** requires that the following rule(s) be met for renewal:
   A. You have experienced improvement in the skeletal characteristics of hypophosphatasia (HPP: genetic disorder causing abnormal development of bones and teeth). Characteristics may include irregularity of the provisional zone of calcification (area on long bone for calcium build-up), physeal widening (area of bone that helps length growth), metaphyseal flaring (a narrow part of long bone grows), radiolucencies (ability to see with x-rays/ radiation), patchy osteosclerosis (parts of abnormal hardening of bone), ratio of mid-diaphyseal cortex to bone thickness, gracile (slender) bones, bone formation and fractures.
   B. You are NOT currently receiving treatment with a bisphosphonate [such as Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)].

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ASFOTASE ALFA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Strensiq.

REFERENCES

- Strensiq [Prescribing Information]. Cheshire, CT: Alexion Pharmaceuticals, Inc.; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 11/15
Client Approval: 05/22
P&T Approval: 04/22