ALBERTA BLUE CROSS®

ASFOTASE ALFA
SPECIAL AUTHORIZATION REQUEST FORM

Please complete all required sections to allow your request to be processed.

Patients may or may not meet eligibility requirements as established by Alberta government-sponsored drug programs.

PATIENT INFORMATION

Patient last name	First name	Initial	Gender M / F	Birth date YYYY	MM	DD	Alberta Personal Health Number

Street address	City	Province	Postal code

ID/client/coverage number	Coverage type	☐ Alberta Blue Cross ☐ Alberta Human Services ☐ Other ______

METABOLIC SPECIALIST INFORMATION

Last name	First name	Initial

Street address	City	Province	Postal code

Telephone number	Fax number	College of Physicians and Surgeons registration number

Date form completed (YYYY-MM-DD)	Last consult date (YYYY-MM-DD)	Metabolic Specialist signature

PHARMACY INFORMATION

Pharmacy name	Telephone number	Fax number

INFORMATION REQUIRED

For **INITIAL COVERAGE (new to drug)**, please complete applicable sections of all pages, and submit together with the consent form.

For **CONTINUED COVERAGE (on drug now or prior use of drug)**, please complete page 1 and the response to therapy section on page 4. For first requests for patients currently/previously on the drug, please complete all pages and submit together with the consent form.

Note: Additional pages may be attached as required; please submit the request form and attachments together.

TREATMENT REQUESTED

Dosage and frequency requested

DIAGNOSIS

☐ **Hypophosphatasia (HPP)**

→ Specify type ☐ Antenatal ☐ Newborn ☐ Infantile ☐ Juvenile (Childhood) ☐ Adult

→ Specify age at onset and nature of first symptom ______

☐ Other, specify ______

CONFIRMATION OF DIAGNOSIS

Does the patient have **perinatal/infantile or juvenile-onset HPP** confirmed by	Yes	No	Details (attach laboratory reports)
a) Genetic testing (documented tissue-nonspecific alkaline phosphatase [TNSALP] gene mutation(s))?	☐	☐	
b) Serum alkaline phosphatase (ALP) level below the age-adjusted normal range?	☐	☐	
c) Plasma pyridoxal-5-phosphate (PLP) above the upper limit of normal established and validated in testing laboratory?	☐	☐	
d) Documented history of HPP-related skeletal abnormalities confirmed radiologically?	☐	☐	

FOR TREATMENT EXPERIENCED PATIENTS

1) Patient is currently on therapy? ☐ Yes ☐ No → specify stop date and reason

2) Indicate initial therapy start date

3) Patient started therapy prior to 18 years of age? ☐ Yes ☐ No

Please mail this request to
- **Alberta Blue Cross, Clinical Drug Services**
  10009 108 Street NW, Edmonton, Alberta T5J 3C5

Or fax to
- **780-401-1150** in Edmonton
- **1-888-401-1150** toll free all other areas

Case number

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Patient's Alberta Personal Health Number (only) ____

ADDITIONAL CLINICAL CRITERIA

System	Details (Check ALL that apply and attach relevant reports)
1) Growth	Current height _________ cm (________ %) Current head circumference _________ cm (________ %) Current weight _________ kg (________ %) ☐ Poor growth ☐ Poor weight gain ☐ Failure to thrive ☐ Growth chart attached Comments
2) Dental	☐ OdontoHPP ☐ Early loss of primary teeth → age at first tooth loss ________ ☐ Poor dentition Comments
3) Skeletal	☐ Severe hypomineralization/osteopenia ☐ Fractures, specify number, location and if non-healing/healed ____________________ ☐ Orthopedic surgical procedures, specify type of surgery, age at procedure ____________________ ☐ Rickets/Osteomalacia ☐ Scoliosis ☐ Skeletal deformities (e.g. knock-knees, bowed legs), specify ____________________ ☐ Craniosynostosis → With systemic signs and symptoms, including muscle weakness, fractures, rickets, pain or nephrocalcinosis, and/or bony disease? ☐ Yes ☐ No ☐ Joint swelling, specify ____________________ ☐ Weakness, specify ____________________ ☐ Abnormal gait/running, specify ____________________ Motor development ☐ Appropriate for age ☐ Delayed → Gross motor delay with substantial skeletal disease? ☐ Yes ☐ No → Delayed walking (>15 months)? ☐ Yes ☐ No ☐ 6 Minute Walk Test result attached ☐ Use of assistive devices, specify ____________________ ☐ Participates in sports ☐ Misses school Patient's/parent's assessment of pain and QOL ____________________ Comments (provide RGIC and Thacher scores)

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ADDITIONAL CLINICAL CRITERIA (continued)

System	Details (Check ALL that apply and attach relevant reports)
4) Pain	☐ Muscle pain ☐ Bone pain ☐ Joint pain Type of pain, location, pain at rest or with activity, daytime or at night ____________ Interventions ☐ Analgesics, specify drug(s) and dose ____________ ☐ Heating pad ☐ Massage ☐ Other, specify ____________ Response to previous interventions ____________ ☐ Visual analog for pain report attached Comments
5) X-ray findings	☐ Skeletal survey, specify age at X-rays, X-ray findings, and most recent X-ray results ____________ ☐ X-ray report attached
6) Renal	☐ Nephrocalcinosis ☐ Renal failure/reduced renal function ☐Lab report attached Comments
7) Respiratory	☐ Lung hypoplasia ☐ Decreased thoracic volume ☐ Respiratory failure ☐ Supplemental O2 required ☐ Assisted ventilation Comments
8) Biochemical	☐ Lab reports attached for calcium, phosphate, magnesium, alkaline phosphatise (ALP), PTH, 25 OH vitamin D, pyridoxal-5-phosphate (PLP), urine phosphoethanolamine (PEA)
9) Other	☐ Hearing Loss, specify ____________ ☐ Seizures → B6 responsive? ☐ Yes ☐ No ☐ Delayed cognitive development, specify ____________ Comments

Additional information relating to request

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▪ **Alberta Blue Cross, Clinical Drug Services** **10009 108 Street NW, Edmonton, Alberta T5J 3C5**	▪ **780-401-1150** in Edmonton ▪ **1-888-401-1150** toll free all other areas	

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MONITORING AND GOALS OF THERAPY

1) Signs and symptoms to be monitored depend on age at diagnosis and may include, in addition to the parameters listed in the "Additional Clinical Criteria" table on page 2 of this form:

For perinatal/infantile HPP: Discontinuation or reduction of ventilatory support, increased mobility (improvement in gait vs. baseline), attainment of age-appropriate gross motor milestones.

For juvenile HPP: Healing of rickets, improvement of bone mineralization and/bony deformities, fewer fractures, less pain, need for less pain medication, improved growth, increased mobility.

Please indicate which clinical, radiological and biochemical parameters and goals of therapy will be monitored for this patient:

2) Documented compliance by patient and family with respect to follow up visits and re-evaluation of laboratory and radiological parameters.

RESPONSE TO THERAPY (update for each request for continuation of therapy, attach additional pages as required)

1) Were the pre-specified goals of therapy met? (include documented signs/symptoms noted above)

2) Were the patient and family compliant with respect to follow up visits and re-evaluation of laboratory and radiological parameters?

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