[Date]

Attn: [Medical/Pharmacy Director], [Department]
[Insurance company]
[Street address]
[City, State, Zip code]

Patient name: [insert text]
Date of birth: [insert text]
Policy #: [insert text]
Group #: [insert text]

Dear [Medical/Pharmacy Director]:

I am writing this letter to appeal the denial of coverage for TYMLOS® (abaloparatide) injection on behalf of my patient.
Patient name:
Patient diagnosis:
Reason for denial:
Date of denial letter:

After further review and based on the clinical assessment of my patient, the diagnosis, and medical history, I am continuing to recommend TYMLOS as the appropriate treatment option. Below is a brief summary of the patient's medical history and rationale for treatment with TYMLOS.

Patient's medical history and treatment rationale:

[Provide a brief statement about the patient's diagnosis and medical history including any underlying health issues that affect your treatment selection. Consider including T-scores at the lumbar spine, total hip, and/or femoral neck, and FRAX score.]

Patient's bone mineral density (BMD) T-score measured by DXA and date obtained	**Fracture site**	**T-score**	**Date**
	Lumbar spine		
	Total hip		
	Femoral neck		

Fracture site(s), prevalent or prior	

List risk factors for fracture (e.g., alcohol intake of 4 or more units a day, smoking, high risk for falls, low body mass, etc.)		**FRAX score**

Prior treatments and response:

[Provide a list of current and past medications, as well as reasons for not prescribing a medication (e.g., contraindications, drug interactions, etc.) and a summary of patient experience for each medication, including clinical outcome, any adverse drug reactions, and length of therapy.]

Past treatment(s)	**Start date(s)**	**Stop date(s)**	**Reason(s) for discontinuation**

[Summary as to why, based on your clinical judgment, your patient requires treatment with TYMLOS.]

My review of the TYMLOS Prescribing Information, the FDA-approved indication, and my clinical experience and opinion serves in aggregate to establish medical necessity for [Patient name.]

Please call my office if you have any questions or require any additional information [Phone number.]

Sincerely,

[Physician's name]

Suggested enclosures: original denial letter, excerpt(s) from patient's medical record, TYMLOS Prescribing Information, and relevant treatment guidelines and clinical trials.

Please see Important Safety Information on next page.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

TYMLOS (abaloparatide) is indicated for the:

- treatment of postmenopausal women with osteoporosis at high risk for fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture), or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, TYMLOS reduces the risk of vertebral fractures and nonvertebral fractures.
- treatment to increase bone density in men with osteoporosis at high risk for fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture), or patients who have failed or are intolerant to other available osteoporosis therapy.

IMPORTANT SAFETY INFORMATION

Contraindications: TYMLOS is contraindicated in patients with a history of systemic hypersensitivity to abaloparatide or to any component of the product formulation. Reactions have included anaphylaxis, dyspnea, and urticaria.

Risk of Osteosarcoma: It is unknown whether TYMLOS will cause osteosarcoma in humans. Osteosarcoma has been reported in patients treated with a PTH-analog in the post marketing setting; however, an increased risk of osteosarcoma has not been observed in observational studies in humans. There are limited data assessing the risk of osteosarcoma beyond 2 years of TYMLOS use. Avoid use of TYMLOS for patients at an increased baseline risk for osteosarcoma including patients with open epiphysis (pediatric and young adult patients); metabolic bone diseases other than osteoporosis, including Paget's disease of the bone; bone metastases or a history of skeletal malignancies; prior external beam or implant radiation therapy involving the skeleton; or hereditary disorders predisposing to osteosarcoma.

Orthostatic Hypotension: Orthostatic hypotension may occur with TYMLOS, typically within 4 hours of injection. Associated symptoms may include dizziness, palpitations, tachycardia, or nausea, and may resolve by having the patient lie down. For the first several doses, TYMLOS should be administered where the patient can sit or lie down if necessary.

Hypercalcemia: TYMLOS may cause hypercalcemia. TYMLOS is not recommended in patients with pre-existing hypercalcemia or in patients who have an underlying hypercalcemic disorder, such as primary hyperparathyroidism, because of the possibility of exacerbating hypercalcemia.

Hypercalciuria and Urolithiasis: TYMLOS may cause hypercalciuria. It is unknown whether TYMLOS may exacerbate urolithiasis in patients with active or a history of urolithiasis. If active urolithiasis or pre-existing hypercalciuria is suspected, measurement of urinary calcium excretion should be considered.

Pregnancy and Lactation: TYMLOS is not indicated for use in females of reproductive potential.

Adverse Reactions:

- The most common adverse reactions (incidence ≥2%) reported with TYMLOS in postmenopausal women with osteoporosis are hypercalciuria (11%), dizziness (10%), nausea (8%), headache (8%), palpitations (5%), fatigue (3%), upper abdominal pain (3%), and vertigo (2%).
- The most common adverse reactions (incidence ≥2%) reported with TYMLOS in men with osteoporosis are injection site erythema (13%), dizziness (9%), arthralgia (7%), injection site swelling (7%), injection site pain (6%), contusion (3%), abdominal distention (3%), diarrhea (3%), nausea (3%), abdominal pain (2%), and bone pain (2%).

Please see Full Prescribing Information at tymlospi.com.