

Where Does PTH Fit in?
Postmenopausal Osteoporosis Treatment Options

Treatment Option	Parathyroid Hormone (PTH)	Estrogen Replacement Therapy (ERT)	Selective Estrogen Receptor Modulator (SERMS)	Bisphosphonates	Salmon Calcitonin
Types	synthetic PTH (teriparatide)	estrogen	raloxifene	alendronate and risedronate	calcitonin
Brand Name	Fortéo®	Various regimens available	Evista®	Fosamax® and Actonel®, respectively	Miacalcin®
Approval	Specific indications uncertain until FDA approval	Prevention and management for postmenopausal women	Prevention and treatment for postmenopausal women	Prevention and treatment for postmenopausal women, men*, steroid-treated	Treatment for postmenopausal women
Form of Administration	Daily injection (subcutaneous)	Pill or skin patch, daily or weekly	Pill daily	Pill daily, Alendronate available in weekly dose	Nasal spray, one spray daily
Other Considerations	To be administered 12- 18 months.	Estrogen taken alone can increase the risk of developing uterine cancer. To eliminate this risk, doctors prescribe the hormone progestin in combination with estrogen. This combination is called Hormone Replacement Therapy (HRT).	Raloxifene may have a protective effect against breast cancer.	Medication should be taken on an empty stomach with a full glass of water first thing in the morning. After taking the medication, remain in an upright position and do not eat or drink for at least one-half hour.	Calcitonin is for women at least 5 years beyond menopause.
Possible Side Effects	May include headaches, leg cramps, nausea.	Slightly elevated risk of breast cancer, deep vein thrombosis.	May include hot flashes & deep vein thrombosis.	May include abdominal or musculoskeletal pain, nausea, heartburn, or irritation of the esophagus.	Runny, irritated nose.

All of these treatments require the intake of adequate calcium (1000-1500 mg/day) and vitamin D (400 IU-800 IU).
 *Alendronate has an indication for men.

Adapted from Data Source: National Institutes of Health Osteoporosis and Related Bone Disease
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New Drug Revolutionizes Osteoporosis Treatment

An Interview with Claude Arnaud, MD, UCSF Professor Emeritus

For the 30 million women and men in the US who suffer bone loss due to osteoporosis, a second chance at youthful bones is around the corner. The FDA is in the process of approving a synthetic form of the naturally occurring hormone PTH (parathyroid hormone). It will be the first drug on the market to actually build bone and to reduce the risk of fractures 60-90 percent.

PTH is a protein hormone made in the body by the parathyroid glands, located in the neck. PTH functions to regulate calcium and phosphate levels in the body. If calcium levels are low, the body releases PTH which directs the bone to release calcium into the body. In premenopausal women this system works well; calcium freed from the bones is quickly replaced. But with the loss of estrogen, the system falls out of balance and postmenopausal women

experience higher bone breakdown and less bone building activity.

In clinical trials using PTH, sponsored by Eli Lilly and Company and the National Institutes of Health under the direction of Dr. Claude Arnaud, professor emeritus of medicine and physiology at the University of California at San Francisco, two-thirds of women experienced restoration of bone mass to its original level of a young normal adult. Low bone mass, osteoporosis and fractures have a domino relationship with each other. Reversing this chain of events is a significant advancement in the treatment of osteoporosis. Upon FDA approval, Eli Lilly and Company is planning to market PTH (teriparatide) under the name Fortéo.

Researchers believe that PTH actually increases osteoblast activity to achieve the net gains of new bone, a phenomenon

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New Drug Treatment

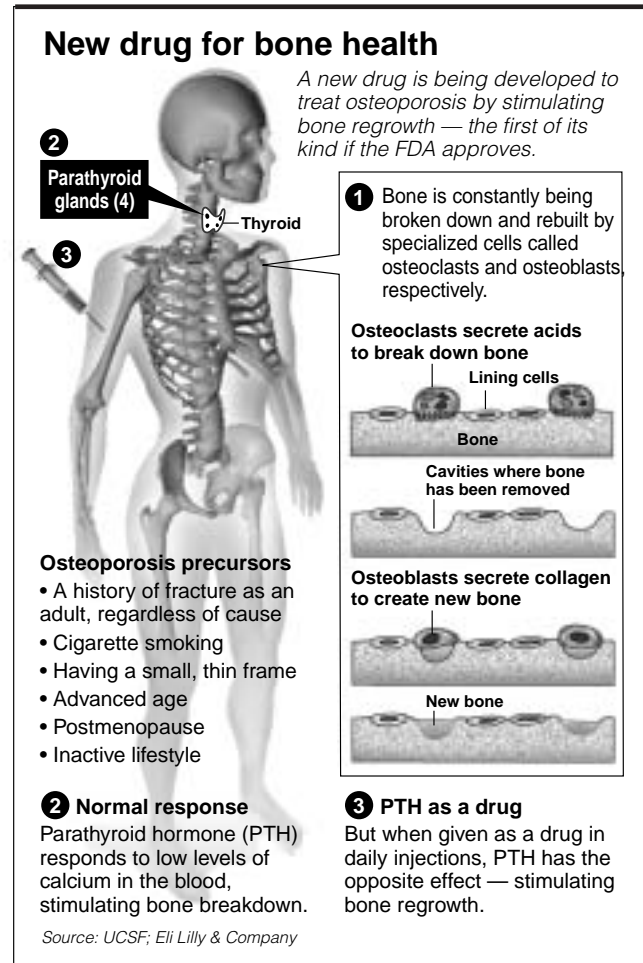
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otherwise only seen naturally in children and young adults. Patients took the drug for about 18 months, and in the trials the risk of new severe vertebral fractures was reduced by 90 percent. With results this compelling, Arnaud believes that the development of PTH brings us closer than ever to curing osteoporosis.

Because PTH is a protein it cannot be taken by mouth and will be available via an injection. Patients will administer it to themselves under the skin, similarly to insulin. These injections will lead to bone gain.

How is it different?

In a recent interview with FORE, Arnaud discussed the mechanism that distinguishes Fortéo from existing osteoporosis drugs. The most commonly used drugs that treat osteoporosis are antiresorptive, which means that they put the brakes on bone breakdown. Depending on the condition of the patient and the drugs used, one might expect a 30-50 percent reduction of vertebral fracture risk over three to four years. Arnaud hypothesizes that antiresorptive drugs are limited in effect because they do not build new bone, but instead fill in the nooks and crannies of recently excavated bone and slow osteoclastic activity. In postmenopause, retarding the bad guys (osteoclasts) also means reducing the



Graphic by John Blanchard ©2001 San Francisco Chronicle

good guys (osteoblasts) that build bone, and so the strength of antiresorptive drugs lies in *maintaining* bone mass and preventing further bone loss. In sum, Arnaud suggests that anti-resorptives are excellent fillers, and their efforts may be given a big boost with the help of PTH.

It stands to reason that people with the lowest bone mass will also experience the most gains with PTH, and so postmenopausal women with bone density T-scores of -3 and lower are obvious candidates. Further study is being performed on the effects with men and premenopausal women with genetically low bone density and history of osteoporosis, and Arnaud has high hopes for both groups.

Is PTH for me?

With all this knowledge, should a patient stop taking his or her antiresorptive drug and switch to PTH? Arnaud advises individuals talk with their health provider about their family's history and perform a bone density screening if appropriate.

It is possible, Arnaud suggests, that the most effective way to use PTH will be immediately before menopause to build up bone to an optimum, normal level, cease its use after 18 months, and take an antiresorptive to maintain the bone mass level. However, anyone with extremely low bone density driven by genetics, regardless of their menopausal status, should experience great gains from PTH as well.

The future

We talked with Arnaud about his vision for osteoporosis care in the future. Because 80 percent of people with osteoporosis in the US are undiagnosed, he is interested in reaching people in new ways and curbing the growing costs of care for baby boomers. Most importantly, he emphasizes that severe osteoporosis is preventable. Bone density screening works, Arnaud says, and with the advent of PTH we have a more complete toolbox than ever before to wipe out fractures.

