## Osteoporosis in Men and Women: An Update on Diagnosis and Management for Fracture Prevention: Part 2

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#### Pharmacologic Therapy

Level of risk and the choice of agents

## Osteoporotic Patients: Level of Risk and Choice of Pharmacologic Agent

**High Risk** (not meeting previous criteria but diagnosed with osteoporosis):

>Postmenopausal women or men over age 50 with a prior hip or spine fracture

>Postmenopausal women or men over 50 with a BMD

T-score of -2.5 or lower at the hip or spine >Postmenopausal women or men over 50 with T-score between -1 and -2.5 at the femoral neck, total hip, or spine if:

- 10 year probability (from FRAX) of hip fracture is ≥ 3%
- 10 year probability of a major osteoporosis-related fracture is ≥ 20%

Camacho PM, Petak SM, et al, American Association of Clinical Endocrinologistal/American College of Endocrinology Clinical Practice Guidelines For The Diagnosis and Treatment of Post Menopausal Osteoporosis- 2020 Update, endocrine Practice, 2020-263-6.

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#### Disclosures

Advisory Board: Astellas Speakers Bureau: Astellas

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## Risk Stratification and Treatment Decisions

#### > Low risk

- No prior fracture, and T-score ≥ -1 and FRAX < 20% MOF, <3% Hip</li>
- Non-pharmacologic treatment. No pharmacologic treatment needed

#### > Moderate risk

- No prior fracture and T-score between -1 and -2.5 and FRAX probabilities <20%MOF, <3% Hip</li>
- Some may benefit from sequential antiresorptive monotherapy especially those with BMD close to -2.5
- Estrogen in early menopause
- Raloxifene in 50's to 60's
- Bisphosphonates mid/late 60's

Camacho PM, Petak SM, et al, American Association of Clinical Endocrinologists/American Codege of Endocrinology Clinical Practice Guidelines For The Diagnosis and Teachment of Pest Menopasual Osleoporosis-2020 Update, endocrine Practice, 2000-26-5-6.

Risk Stratification and Treatment

#### Decisions High risk

> Older single prior fracture (> 2 years earlier) or T-score -2.5 or T-score -1 to -2.5 with FRAX ≥20% MOF or ≥3% Hip

Goal: Improve BMD to T-score >-2.5 and reduce fracture risk

- Younger women may benefit from estrogen/raloxifene especially if spine T-score is low and hip is > -2.5
- Usually bisphosphonates or denosumab
- Anabolic agents are appropriate for some

Camacho PM, Petak SM, et al, American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines Fo The Diagnosis and Treatment of Post Mesopassal Osteoprosis-2020 Update, endocrino Practice, 2020:26:5-6.

## Osteoporotic Patients: Level of Risk and Choice of Pharmacologic Agent

#### Very High Risk:

- > Recent fracture (within the last 12 months)
- > Fractures while on approved drug therapy, multiple fractures, fractures while on drugs causing skeletal harm (i.e. glucocorticoids)
- > Very low T-score (e.g. less than -3.0)
- > High risk for falls or history of injurious falls
- > Very high fracture probability by FRAX
  - Major osteoporotic fracture >30%
  - Hip fracture >4.5%

Camacho PM, Petak SM, et al, American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines Fo

#### Choosing a Pharmacologic Agent

Approved agents with efficacy to reduce hip, nonvertebral and spine fractures as initial therapy:

- > High fracture risk:
- Alendronate, risedronate, zolendronate, denosumab appropriate
- > Very high fracture risk:
  - Abaloparatide, denosumab, romosozumab, teriparatide, and zoledronic acid
    - And consider for patients who are unable to tolerate oral therapy

Camacho PM, Petak SM, et al., American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines For The Diagnosis and Treatment of Post Menopausal Osteoporosis-2020 Update, endocrine Practice, 2020;265-6.

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#### Anabolic Agents and Treatment Sequence in Appropriate Patients

- > Recent trials have changed the thinking on when to use anabolic agents:
  - Not a drug of "last resort"
  - After multiple fractures
  - Failure of other medications
- > The three anabolic agents (teriparatide, abaloparatide and romosozumab) reduce non-vertebral and vertebral fractures faster and to a greater extent than potent antiresorptive agents

ssman F, Anabolic Therapy and Optimal Treatment Sequences for Patients With Osteoporosis at High Risk for Fracture, Endocrine action, Accepted for Publication. 2020

#### Anabolic Agents and Treatment Sequence in Appropriate Patients

- > Sequence of drug therapy matters
- Bone density accrual is maximized when the anabolic agent is given first and followed with antiresorptive therapy
- Total hip score is considered the best measurement for future fracture risk
- Obtaining a greater hip BMD is a treatment goal for high risk osteoporosis patients

Cossman F, Anabolic Therapy and Optimal Treatment Sequences for Patients With Osteoporosis at Hig

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#### Anabolic Agents and Treatment Sequence in Appropriate Patients

Identifying appropriate patients for anabolic therapy:

- > Patients with prior fractures
- > Patients who present with very low BMD (T-score below -3.0) even in the absence of prior fracture
  - Especially with other risk factors such as advanced age, high fall risk, physical or cognitive disability

Cossn an F, Anabolic Therapy and Optimal Treatment Sequences for Patients With Osteoporosis at High Risk for Fracture, Endocrine Practice, Accepted for Publication, 2020

Initiating Pharmacologic Therapy: Case Examples

Fracture risk	Case example	Initial treatment	
		consideration	
Moderate	60-year-old female; lumbar spine T score -2.5, femoral	Raloxifene (especially if patient is interested in	
	neck T score -1.2	breast cancer prevention) or a bisphosphonate	
High	70-year-old female; femoral neck T score -2.7; history	Bisphosphonate if no significant renal dysfunction	
	of hip fracture in parent	(oral if tolerated or IV infusion) or denosumab	
High	80-year-old female: lumbar spine T score -0.9, femoral neck T score -1.7, FRAX score: major osteoporotic fracture 10-year risk: 15%;	Bisphosphonate if no significant renal dysfunction (oral if tolerated or IV infusion) or denosumab	
	hip fracture 10-year risk: 3.9%		
Very high	78-year-old female, femoral neck T score -3.1, vertebral	Consider sequencing with: teriparatide, abaloparatide,	
	compression fracture diagnosed on x-ray	or romosozumab initially and follow with a maintenance antiresorptive drug	

#### Monitoring Pharmacologic Treatment

- > Repeat DXA every 1 to 2 years until findings are stable
- > The 1/3 radius may be considered as an alternate site when the lumbar spine/hip are not evaluable
- > Continue to follow every 1 to 2 years depending on the clinical circumstances
- > Bone turnover markers may be used to assess patient compliance and efficacy of therapy.

Camacho PM, Petak SM, et al, American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines For The Diagnosis and Treatment of Post Menopassal Outeopprosis-2020 Update, endocrine Practice, 2020;26:5-6.

## How to Determine if Treatment is Successful

- > Stable or increasing bone mineral density
- > No evidence of new fractures or vertebral fracture progression
- > One new fracture may not necessarily be evidence of treatment failure
- > Consider two or more fragility fractures as evidence of treatment failure

Camacho PM, Petak SM, et al, American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines
For The Diagnosis and Treatment of Post Meropassal Osteoporosis - 2020 Update, endocrino Practice, 2020-26-5-6.

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#### Length of Treatment

- > Abaloparatide and teriparatide treatment is 2 years
  - Follow with a bisphosphonate or denosumab
- > Romosozumab is 1 year and follow with a drug intended for long term use
- > Oral bisphosphonate
  - Consider drug holiday after 5 years if fracture risk is no longer high
  - Such as T- score is greater than -2.5
  - No fractures
  - Continue up to 10 years if fracture risk remains high

Camacho PM, Petak SM, et al. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines For The Diagnosis and Treatment of Post Menopausal Osteoporosis - 2020 Update, endocrino Practice, 2020:26:5-6.

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#### Length of Treatment

- > Oral therapy
  - Consider a drug holiday after 6 to 10 years of stability in patients with very high fracture risk
- > IV infusion with zoledronic acid
  - Consider a drug holiday after 3 years in high-risk patients or until fracture risk is no longer high
- Continue up to 6 years in very-high risk patients

Camacho PM, Petak SM, et al, American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines For The Diagnosis and Treatment of Post Menopausal Osteoporosis-2020 Update, endocrine Practice, 2020;26:5-6.

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#### Drug Holiday

- > End is based on individual patient circumstances such:
  - An increase in fracture risk
  - Decrease in bone mineral density
- Increase in bone turnover markers
- > NEVER START A DRUG HOLIDAY WITH NON-BISPHOSPHONATE ANTIRESORPTIVE DRUGS
- > If denosumab is discontinued, patient should be transitioned to another antiresorptive

Camacho PM, Pelak SM, et al., American Association of Clinical Endocrinologistal/American College of Endocrinology Clinical Practice Guidelines For The Diagnosis and Treatment of Post Manopausal Osteogonosis- 2020 Update, endocrine Practice, 2020-26:5-6. Addressing Recent Controversies in the Treatment of Osteoporosis

#### Addressing Recent Controversies

- > Long term use of bisphosphonate therapy
- > Bisphosphonate therapy and the occurrence of fractures of the subtrochanteric or diaphyseal femur
- > Osteonecrosis of the jaw (ONJ)

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#### Addressing Recent Controversies

- > Treatment decisions require risk and benefit discussions
- > What was acceptable risk previously, may no longer be acceptable
- > If disease state risk is high: fracture
  - Risk of rare complications may be outweighed

Effective Patient Management in the Primary Care Setting

#### Bisphosphonates

- > Concerning adverse effects:
- Osteonecrosis of the jaw
  - Risk 1:1,000 to 1:263,000
  - · Not associated with treatment duration
  - Potential risk factors include poor oral hygiene, glucocorticoid therapy, and chemotherapy
- Atypical femur fractures
  - Risk increases with longer therapy duration
- Subtrochanteric and diaphyseal femoral fractures
- > Bisphosphonates accumulate in the bone, so drug holidays are recommended to reduce long-term risk

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#### **Drug Holiday Recommendations**

Risk level for fracture	Initiate drug holiday	Therapy during holiday	Length of holiday
High risk	After 5 y of stability on oral treatment or after 3 y with intravenous zoledronic acid	None	Individualize to patient risk
Very high risk and remains at high risk	After 10 y of oral therapy or after 6 y for intravenous zoledronic acid	Consider teriparatide	Individualize to patient risk

Camacho PM, Petak SM, et al, American Association of Clinical Endocrinologiata/American College of Endocrinology Clinical Practice Geldeline For the Chagnosis and Treatment of Post Manopassal Obseptionals—2020 Update, en

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## Effective Patient Management in the Primary Care Setting

Patients may need in depth counseling on why treatment is recommended:

- > Patients may not be compliant to treatment regimens if they do not understand the risk of something (low bone mass) and increased fracture risk, when they don't feel symptoms
- > Based on a patient's level of education, they may require more detail on their BMD, FRAX or treatment recommendations

THIS REQUIRES TIME!

## Osteoporosis and Fracture Prevention in the Primary Care Setting

- Patients need to participate in shared decision making regarding starting pharmacologic therapy as treatment or for preventative care for significant 10 year fracture risk
- Patients need to understand the idea of risk and benefit when they decide whether they will take medication

Educational Gaps and Opportunities

- > Current guidelines for who to screen
  - Decreased reimbursement by Medicare for bone densitometry
  - Underscreening of women and men and low rate of Medicare coverage
- > Current guidelines for who to treat:
  - Identification of patients who are untreated after a hip or spine fracture
  - Identification of patients who have not had appropriate BMD testing
  - Utilization of FRAX to identify osteoporotic patients who are not yet osteoporotic by T- score

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#### **Educational Gaps and Opportunities**

- > Keeping up with controversies and options for changing medication, drug holiday and continuation of rank ligand inhibitor
- > Consideration of anabolic agents in appropriate patients and setting up a referral source if the clinician is not comfortable initiating the treatment
- > Having dialogue with specialists when indicated for consultation on appropriate therapy with chronic kidney disease and other conditions
- > The need for individualization of treatment plan includes the need to avoid overtreatment

Potential Missed Opportunities!

- > BMD testing in women 65 and older
- > BMD testing in men 70 and older
- > Treatment of men and women at high 10 year fracture risk by FRAX who are not yet osteoporotic
- > Vertebral or hip fracture history
- > Women on aromatase inhibitor therapy
- > Men on androgen-deprivation therapy for prostate cancer
- > Men and women on glucocorticoid therapy

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#### Summary

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- > Osteoporosis is under diagnosed and preventative care is under utilized
- > Current practice requires dialogue between patient and practitioner in regards to individual risk and risk and benefits of therapeutic options
- > Treatment strategies must be individualized to obtain greater compliance to therapy
- > Practitioners will need to stay current while treatment recommendations continue to be reviewed and possibly changed

Cases: Very high risk for fracture

BMD FRAX

The Art of Managing Osteoporosis and Fracture Prevention!

76 yo Caucasian female: menopause at age 55. 64 inches tall, 170 lbs. hypertensive, hyperlipidemia, type 2 DM.

10/7/21 BMD: right and left hip: -2.0 and -3.2

right and left femoral neck: -3.0 and -4.0 Change from BMD: 10/14/15

LS 2.9%, left femoral neck -20.3%, right femoral neck -10.4%

FRAX: Major osteoporotic fracture: 35.8%

Hip: 19.9%

Case #1

- > What is her fracture risk?
- > What is the patient's desire for treatment
- > What is the patient's insurance coverage?
- > What are the important medical history questions?
- > What labs would you draw?
- > How would you treat this patient?
- > Would you refer this patient?

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#### Case #2

82 yo woman

LS: normal with -0.9

Hip: Moderate low bone mass (Osteopenia) -2.0

Patient has never been treated with pharmacologic therapy. She denies problem with swallowing, GERD or known esophagus problem. She has mild CKD and is being followed by a nephrologist.

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## Would you treat this patient? What would you prescribe?



#### Case #3

76 yo Caucasian female, menopause at 51. Hypertension, type 2 DM, hyperlipidemia. GERD. Normal kidney function. 12/6/22 T-score right and left hip: 0.5 and 0.2. Right and left femoral neck -0.6 and -0.3.

Forearm: -3.7. Has completed 2 infusions of zoledronic acid and last one was one year ago.

Change from previous BMD: 9/17/20 Forearm: -3.0

What will you recommend that the patient does at this time?

80 yr old Caucasian patient presents for a 1st visit. History of hypertension and hyperlipidemia

- She states that she took a pill for osteoporosis for a few years and then was switched to denosumab. After 7 years on the drug, she developed a severe blistering skin rash. Saw 2 dermatologists and had 2 skin biopsies that were reported as non-specific inflammatory change.
- She was advised to stop the denosumab and has not taken any osteoporosis therapy for the last 2 years.
- > She never smoked. No history of hip fracture in parent. No history of adult fracture. Not diabetic. Walks regularly for exercise.
- > Reports adult height loss of 2 inches

Height: 4'8

Weight: 100 pounds

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#### Case #4

How would you manage this patient? Questions:

- > What pharmacologic therapy would you recommend?
- > What about patient counseling regarding choices?
- > Will you consider denosumab and would the patient take it?
- > What are the risks and benefits of options?
- > What did the patient prefer and why?

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#### Case #5

Case #4

T-scores: LS -3.6

Hip: 12%

Left femoral neck: -3.4

Total hip: -2.4%

Change from previous: LS -14.6%

FRAX: Major Osteoporotic Fracture: 27%

Total hip: -2.1

BMD:

67 yr old has her 1<sup>st</sup> bone density test. She reports menopause at age 48. On medication for hypertension and hyperlipidemia. No history of adult fracture, no hip fracture in parent, never smoked, occasional glass of wine. Exercises regularly

BMD:

Right and left total hip: -2.9 and -2.8 Femoral neck: -3.1 and -3.5

LS -1.2

FRAX:

40

Major Osteoporotic Fracture: 23.1%

Hip Fracture: 9.3%

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#### Case #5

How would you manage this patient? Questions:

- > Does she require a work-up regarding secondary causes of osteoporosis?
- > What pharmacologic therapy would you recommend?
- > What about patient counseling regarding choices?
- > What are the risks and benefits of options?
- > What did the patient prefer and why?

> Is she a candidate for anabolic therapy?

Case #6

78 yr old black woman with dementia who lives with her husband. Has been taking oral bisphosphonate for 2 years. According to her husband, she takes it once a week and waits 30 minutes before eating, drinking, or laying d

Normal kidney function. No history of adult fracture. No hip fracture in parent. No diabetes.

BMD

Right and left total hip: -2.9 and -3.1 Right and left femoral neck: -2.8 and -3.1

LS: -1.2

FRAX: Major Osteoporotic Fracture: 11.6%

Hip: 4.7%

## Case #6 BMD Change from previous BMD 2 years ago: > LS -5.4% > Left Total hip: -10.2% > Right Total hip: -11.4% 43 Deep Dive More cases from the trenches 45 Case #1

#### Case #6

How would you manage this patient? Questions:

- > What pharmacologic therapy would you recommend?
- > What about patient counseling regarding choices?
- > Will you consider denosumab and would the patient take it?
- > What are the risks and benefits of options?
- > What did the patient prefer and why?

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Just a Reminder: When considering plan...

- > Calcium and Vitamin D
- > Labs
- > Upcoming tooth extraction or tooth implant
- > History of acid reflux
- > Fall prevention
- > Kidney function
- > Mentation
- > Insurance
- > Patient's preference

59 yo Black female with history of surgical menopause at age 34. Took estrogen for only a few years after surgery. Healthy. No kidney disease. No diabetes or hypertension.

BMD: right and left total hip: -2.4 -3.1 right and left femoral neck: -2.6 -2.9

Lumbar spine: -2.5 Is she osteoporotic?

Is she at high or very high risk of fracture?

What would you suggest for treatment?

What labs would you draw?

#### Case #1

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- > Pt is interested in anabolic therapy after discussion of the option due to her low bone density.
- > What are her options?
- What are the logistics in trying to start her on an anabolic agent?

74 yo black female: History per diagnostic center
-hysterectomy at age 30. Relates steroid use of
unspecified duration. History of RA.
BMD: right and left hip: -0.7 and -0.5
right and left femoral neck: -2.4 -1.9
Loss at all levels from previous: 7% and 8.7%

Information Provided by Testing Center

Questionnaire:

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# Recalculation After Taking History From Patient Pt denies being on glucocorticoid therapy or having had a fracture.

Country: US (Black)

Questionnaire:

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Case #3

86 yo black female with hysterectomy at age 57.

BMD: right and left hip: -2.4 -2.3 right and left femoral neck: -2.7 -2.1 What questions would you ask the patient? Does she need labs?

What would you prescribe?

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#### Case #4

71 yo white male: Pt has been on oral alendronate for 2 years.

BMD: right and left hip: -2.4 -2.5 right and left femoral neck: -2.9 -2.6 Lumbar spine: -0.6

Values represent a loss of bone mineral density at the right and left hips: 2.7% and 2.4%

#### Case #4

- > What is his fracture risk?
- > What is the patient's desire for treatment
- > What is the patient's insurance coverage?
- > What are the important medical history questions?
- > What labs would you draw?
- > How would you treat this patient?
- > Would you refer this patient?

- > Serum calcium, PTH, testosterone free and total, TSH, protein electrophoresis: WNL
- > 24 hour urine:
  - Calcium, creatinine, sodium: WNL
  - N-Teleopeptide: elevated to 784 (Normal range male: 21 - 83)
- > What does this mean? Pt has been on an antiresorptive agent for 2 years

Case #5

72 yo white male with current smoking history and diabetes

BMD: right and left total hip: -2.1 -3.4 right and left femoral neck: -1.5 -2.2

FRAX: MOF: 13.8 Hip: 6.4

What labs would you order?
What are your options for pharmacologic therapy?

## Case #6

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79 yo female with menopause at age 53. Pt has never taken any medication for fracture prevention.

BMD: right and left total hip: -3.5 -3.4 right and left femoral neck: -3.5 -3.1

FRAX: MOF: 34% Hip: 16.6

What are your options for treating this patient? What labs would you obtain?

Case #6

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- > What is her fracture risk?
- > What is the patient's desire for treatment
- > What is the patient's insurance coverage?
- > What are the important medical history questions?
- > What labs would you draw?
- > How would you treat this patient?
- > Would you refer this patient?

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#### Case # 6

- > What would you discuss regarding sequencing with anabolic therapy?
- > What are the risks and benefits?
- > If pt agrees and she did, what are the logistics?

Case #7

74 yo black female with surgical menopause at age

BMD: Total hip: -2.4 -2.5 Femoral neck: -2.4 -2.3 LS: -0.6

FRAX: MOF: 7.1% Hip: 2.1%

- > What is her fracture risk?
- > What is the patient's desire for treatment
- > What is the patient's insurance coverage?
- > What are the important medical history questions?
- > What labs would you draw?
- > How would you treat this patient?
- > Would you refer this patient?

Case #8

78 yo white female with history of surgical menopause at age 37.

BMD: Right and left total hip: -0.2 -0.4 Right and left femoral neck: -1.7 -1.3

LS: 1.4

FRAX: MOF: 20% Hip: 4.6%

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#### Case #8

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- > What is her fracture risk?
- > What is the patient's desire for treatment
- > What is the patient's insurance coverage?
- > What are the important medical history questions?
- > What labs would you draw?
- > How would you treat this patient?
- > Would you refer this patient?

Resources

Bone Health and Osteoporosis Foundation www.bonehealthandosteoporosis.org

North American Menopause Society (NAMS) www.menopause.org

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#### TREASURE YOUR BONES AT EVERY AGE!



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