PROTOCOL FOR PATIENTS WITH ABNORMAL LAB AND X-RAY VALUES

Patients newly diagnosed as osteopenic or osteoporotic on a radiology report or patients receiving abnormal lab values on the following lab tests are appropriate candidates for the Bone Densitometry Disease Management Program (BDDMP):

- Vitamin D lab value under 32 (for patients over age of 50)
- TSH lab value under 0.270
- PTH lab value over 65
- Calcium lab value under 8.3
- Testosterone lab value under 280 (for patients over age of 50)
- Urine Calcium Clearance lab value under 6.8 or over 21.3

If a patient meets the criteria above, but is under the age of 25, the primary care physician will be engaged to determine if testing is appropriate.

Any patient who has received bone density testing within the previous 24 months at another facility will be asked to have the results forwarded to their primary care physician at Lakeside Family Physicians or Lakeside Primary Care for review to determine if testing is appropriate.

For tracking purposes, in the event a patient has had bone density testing at an external facility, a designated member of the healthcare team will complete the bottom portion of a bone density referral form and enter the information into the referral tracking software while awaiting receipt of the results. If results are not received within the timeframe prescribed (see Referral Policy), a member of the healthcare team will make a second attempt to obtain prior bone density testing results from the external facility. Should the second attempt to obtain results fail, the primary care physician will receive notification to determine appropriate course of action.

If a bone density exam is indicated per the pathway criteria above and no testing has occurred within the previous 24 months, a bone density referral form will be completed and patient will be contacted by the BDDMT to schedule an appointment. See referral policy that includes instructions relating to non-compliance if for any reason a bone density test cannot be scheduled.

BONE DENSITY RECALL PROGRAM

If the initial bone density scan results show a diagnosis of osteopenia or osteoporosis, the patient will be entered into the automated recall program. The BDDMT will initiate a subsequent bone density scan two years from the most recent study to monitor response to patients’ individualized plan of care (i.e., increase Vitamin D, Calcium supplement, Forteo, ReClast, Boniva, Prolia, etc.)
Labs
If patient is being treated with prescribed medication and followup or recall study reveals a loss in bone density, the following labs will be ordered: PTH, vitamin D 25OH, TSH and 24-hour urine for calcium. Testosterone levels will be ordered for male patients. Technologist to review labs, within 90 days, to avoid duplicate testing.

Primary Care Physician Communication
Follow-up appointment to be scheduled by BDDMT with the patient’s primary care physician within two weeks from the bone density exam and labs. Physician will have all results available for review during follow-up visit.

BONE DENSITY TESTING REPORTS

Patient Biographical
The patient biographical information is obtained from physician referral and verified by patient’s verbal history. Height is measured by stadiometer to ensure accuracy. Weight is obtained on day of scan.

Densitometry Results
Sites reported include AP Spine, Dual Femur Neck Left and Total Femur, and Dual Femur Neck Right and Total Femur. Forearm results are listed if the site is scanned.

T-scores are reported and classified as normal, osteopenia or osteoporosis according to the WHO classification. Percent Change vs. Previous is the percentage of change in the BMD since the last study.

Previous study must have been performed at Lakeside Family Physicians to ensure precision of change. Significant change notifies physician if a real biologic change has occurred based on the precision of the technologists. This change is based on BMD change and not T-score changes. T-scores can change due to updated reference changes or slight BMD changes. BMD changes outside of the least significant change represent a gain or loss of BMD which aides the physician in continuing, discontinuing or changing therapy.

The BDDMT has performed an average Precision Assessment to determine Lakeside Family Physician’s precision error and calculated the Least Significant Change. Precision Assessment included measuring 15 patients three times each scan site. When reporting results for a follow-up or recall measurement a positive result indicates there has been a significant change in BMD and a negative result indicates there has not been a significant change in BMD when compared to previous study.
Assessment
The assessment lists the area with the lowest T-score and WHO classification as well as any additional testing or exclusions. The results of the WHO absolute fracture risk model (FRAX) can also be found in the assessment portion of the report.

Patients who are considered to be osteoporotic OR osteopenic with high risk of fractures based on FRAX will be scheduled a followup appointment with their physician. Osteoporotic patients will have osteoporotic lab panel drawn on same day as DXA so the physician will have all results during scheduled patient follow-up.

Recommendations
Recommendations for treatment follow the National Osteoporosis Foundation (NOF) guidelines. NOF recommends treatment for patients with a T-score of 02.5 and below at femoral neck or spine AFTER appropriate evaluation to exclude secondary causes, patients with hip or vertebral (clinical or morphometric) fracture or postmenopausal females and men age 50 and older with T-score between -1.0 and -2.5 at the femoral neck or spine AND a 10-year hip fracture probability 3% or greater or a 10-year major osteoporosis-related fracture probability 20% or greater based on the WHO absolute risk model (FRAX).

Treatment options are listed as follows:
Postmenopausal women with osteopenia and high risk of fractures have recommended treatment options of Fosamax, Actonel, Boniva oral, Reclast, Calcitonin, Evista and hormone replacement therapy.

Men over 50 with osteopenia and high risk of fractures have recommended treatment options of Fosamax, Actonel, Boniva oral, Reclast, Calcitonin and testosterone replacement therapy.

Postmenopausal women with osteoporosis have recommended treatment options of Fosamax, Actonel, Boniva IV and oral, Reclast, Calcitonin, Evista and hormone replacement therapy.

Men over 50 with osteoporosis have recommended treatment options of Fosamax, Actonel, Boniva IV and oral, Reclast and Calcitonin.

Each patient will be instructed on dietary calcium/calcium supplements, vitamin D, weight bearing exercises, and muscle strengthening exercises. Patient education handouts are included with this packet.

Follow-up
Follow-up bone density testing intervals are determined according to each patient’s clinical status: typically one year after initiation or change of therapy.
and two years to determine whether treatment should be started on untreated patients, and to monitor response to therapy by finding an increase or decrease in bone density, which could suggest the need for reevaluation of treatment and evaluation for secondary causes of bone loss.

Follow-up appointment will be scheduled with physician if patient is newly diagnosed or untreated osteopenic with high risk of fractures, or newly diagnosed or untreated osteoporotic patient or osteoporotic patient with significant loss of BMD.

If patient is newly diagnosed osteoporotic then labs for secondary causes will be drawn so physician will have bone density report and labs available at follow-up appointment. Those labs include PTH, vitamin D 25OH, TSH and 24 hour urine for calcium. Testosterone levels will be performed on men. Technologist will review recent labs to avoid duplicate testing.

**ESTIMATED CREATININE CLEARANCE**

The estimated creatinine clearance is needed for Reclast infusion (should be above 35mL/min) and Boniva injection (should be above 30mL/min).

Carilion Labs are unable to calculate the estimated creatinine clearance. The Glomerular Filtration Rate is not the same as the estimated creatinine clearance.

The following calculation is used to calculate the estimated creatinine clearance:

Cockroft-Gault: \[
\frac{140 \text{- age}}{72 \times \text{serum creatinine}} \times \text{wt (kg)}
\]

For women: multiply above x 0.85

According to the International Society for Clinical Densitometry (ISCD), the Joint Commission, World Health Organization (WHO), and National Osteoporosis Foundation (NOF) the following guidelines are indications for Bone Mineral Density (BMD) testing:

Women age 65 and older

Postmenopausal women under age 65 with risk factors for fracture*

Women during the menopausal transition with clinical risk factors for fracture*

Men aged 70 and older

Men under age 70 with clinical risk factors for fracture*
Adults with fragility/pathological fracture without trauma

Adults with a disease or condition associated with low bone mass or bone loss (hyperparathyroidism, gastric bypass, anorexia, bulimia, chronic liver or kidney disease, hypogonadism, vitamin D deficiency, hyperthyroidism, COPD, Cushing’s Syndrome, elite athlete with prolonged amenorrhea, hemochromatosis, hemophilia, inflammatory bowel disease, diabetes Type I, multiple sclerosis, celiac sprue, thyrotoxicosis, osteomalacia, Paget’s Disease, rheumatoid arthritis, hypercalcemia, hypercalciuria)

Adults taking medications associated with low bone mass or bone loss (steroids, anticonvulsants, long term heparin use, aromatase (Arimidex) therapy for breast cancer, Luprox therapy for prostate cancer, chemotherapy, DepoProvera)

Anyone being treated to monitor treatment effect

Anyone not receiving therapy in who evidence of bone loss would lead to treatment

*Risk factors for fracture:

History of parental hip fracture
Personal history of fragility fracture after age 40
BMI less than 19
Solid organ or bone marrow transplantation
Alcoholism (3 or more drinks daily)
Smoker
Immobilization (paraplegic)
Height loss (historical height loss greater than 1.5” in women and 2.5” in men or documented height loss greater than ¾” in women and 1” in men)
Kyphosis
Estrogen deficient (postmenopausal female not on hormone therapy)

**LAB TESTS TO RULE OUT SECONDARY CAUSES OF OSTEOPOROSIS**

The National Osteoporosis Foundation recommends ruling out secondary causes of osteoporosis before starting patients on pharmacological treatment.

The American Association of Clinical Endocrinologists Guidelines for Clinical Practice for the Prevention and Treatment of Postmenopausal Osteoporosis suggests laboratory evaluations to establish baseline conditions or definitely exclude secondary causes of osteoporosis.

The following Osteoporosis Lab Panel will be performed on newly diagnosed or presently untreated patients who are determined to be osteoporotic by WHO criteria:
TSH
Vitamin D 25 OH
PTH
24 hour urine for calcium
Testosterone (men only)

These labs will be forwarded to patient’s physician along with DXA Report to review at patient’s followup appointment. Technologist will review recent labs to avoid duplicating tests.

Additional laboratory evaluations suggested by AACE are:
CBC
Calcium
Phosphorus
Total protein
Albumin
Liver enzymes
Alkaline phosphatase
Creatinine
Serum thyrotropin
ESR

PATIENTS RECEIVING FORTEO PROTOCOL

Bone Densitometry Disease Management Team will verify patient’s insurance benefits.

Appointment will be scheduled by Technologist in Room 21.

Technologist will review side effects, warnings, and medication storage.

Technologist will perform injection training which will include patient giving themselves their first injection while in the office. One 28-day Forteo pen and travel bag with cold packs will be given to patient, which is supplied by Lilly.

Technologist will instruct patient to continue calcium 600mg and vitamin D 400 IU twice daily throughout the course of therapy.

Technologist will complete Forteo consult form and return to physician.

PATIENTS RECEIVING RECLAST PROTOCOL

Bone Densitometry Disease Management Team will verify estimated creatinine clearance and verify patient’s insurance benefits.
Technologist will discuss benefits, medication indication, side effects and Osteonecrosis of the Jaw (ONJ). Patient will be instructed to drink at least two 8oz glasses of water before coming for infusion. Patient will be instructed to continue calcium 600mg and vitamin D 400 IU twice each day throughout the course of treatment.

Appointment will be scheduled by Technologist in Room 42 on Tuesday, Wednesday and Thursday at 2pm, 3pm and 4pm.

RN will perform vitals: BP, pulse and respirations. RN will verify patient drank 16oz of water prior to appointment. If patient failed to drink the water prior to appointment RN will have the patient drink 16oz of water prior to infusion.

Reclast is infused at least 20 minutes.

RN will review again side effects and calcium and vitamin D supplements. Patient will be instructed to drink plenty of fluids throughout the remaining day. Patient will be given Reclast starter kit provided by Novartis which contains calcium supplements as well as side effect information.

RN will perform vitals: BP, Pulse and respirations.

RN will sign Reclast Infusion Protocol form and return to Bone Density Technologist.

Bone Density Technologist will collate all information and will send to physician’s office.