The information contained in this protocol should never be used as a substitute for clinical judgment.

The clinician and the patient need to develop an individual treatment plan that is tailored to the specific needs and circumstances of the patient.
Osteoporosis Treatment Protocol

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OSTEOPOROSIS SCREENING

INDICATIONS FOR MEASURING BASELINE BONE MINERAL DENSITY

1. Women aged 65 and older.
2. Postmenopausal women under age 65 and men age 50-69 with risk factors.
3. Men aged 70 and older.
4. Adults with a fragility fracture.
5. Adults with a disease or condition associated with low bone mass or bone loss.
6. Adults taking medications (e.g. glucocorticoids, > 5 mg/day of prednisone or its equivalent for > 3 months) associated with low bone mass or bone loss.
7. Anyone being considered for pharmacologic therapy.
8. Anyone being treated, to monitor treatment effect.

Refer to Page 3
Changes in lifestyle if indicated:

**ADEQUATE CALCIUM:** At least 1200 mg per day – See Page 18.

**ADEQUATE MAINTENANCE VITAMIN D:** D\textsubscript{2} (ergocalciferol) 50,000 units twice a month or D\textsubscript{3} (cholecalciferol) 1000 to 2000 units daily.

**EXERCISE REGULARLY:** A safe, regular exercise program, tailored to the patient’s individual capabilities and needs is necessary to maintain a strong musculoskeletal structure. Avoid activities that cause compressive forces on the spine, and avoid deep flexion of the spine; either activity can encourage vertebral compression fractures to occur.

**FALL PREVENTION:** Reducing a patient’s risk of falling inside and outside the home decreases a patient’s risk of incurring a fracture. Eliminate hazardous obstacles; improve vision with adequate lighting and regular eye care. Consider home care, home safety and if appropriate, use CDC fall prevention checksheet for patient education (Page 26).

**REDUCE CAFFEINE INTAKE:** Excessive caffeine reduces mineralization from the skeleton and increases renal excretion of calcium.

**REDUCE ALCOHOL INTAKE:** Excessive alcohol appears to increase an individual’s risk of osteoporosis.

**STOP SMOKING:** Smoking increases a patient’s risk of osteoporosis.

- Document education in lifestyle recommendations in all patients at risk for and with osteopenia or osteoporosis at least once a year.
Osteoporosis

DXA Scan results

BMD (T-score) > -1.0 SD
No treatment
Monitor DXA scan every 5 years or sooner if patient develops new risk factor for osteoporosis or develops fragility fracture of hip, vertebral body or wrist

BMD (T-score) between -1 and -1.5 SD
Refer to page 5

BMD (T-score) ≤ -1.5 SD to ≥ 2.5 SD
Refer to page 6

BMD (T-score) < 2.5 SD
Refer to page 7

New fragility fracture
Refer to page 7

BMD (T-score) -1 to -1.5 SD
Refer to page 4

BMD (T-score) ≤ -1.5 to ≥ -2.5 SD
Refer to page 5

BMD (T-score) < -2.5 SD
Refer to page 6
BMD (T-Score) between -1 and > -1.5 SD

Significant risk factors for the development of osteoporosis?

Yes

No

Repeat DXA yearly if patient on chronic steroids
Or Repeat DXA every 2 years if patient not on chronic steroids

Refer to page 5

Refer to page 6

Refer to page 8

T-Score -1 to -2.5 and 10-year probability of hip fracture ≥ 3% or a 10-year probability of any major osteoporosis-related fracture ≥ 20% based on the US adapted WHO algorithm

Does patient have?
Prior osteoporosis related fracture other than hip or vertebral
Or
Secondary cause associated with high risk of fracture such as chronic glucocorticoid use or total immobilization
Or
BMD (T-score) < -2.5 SD

New fragility fracture of hip, vertebral (clinical or morphometric) or wrist

Refer to page 7

Repeat DXA scan 5 years or if patient develops osteoporosis related fracture

Refer to page 2

Workup secondary cause of low BMD Refer to page 16

Was secondary cause present?

Yes

Refer to page 1

No

Treat secondary cause

Refer to page 2

Refer to page 8

Refer to page 5

Refer to page 6

Refer to page 7
**Workup for secondary cause of low BMD**
Refer to Page 16

Was secondary cause present?

**Does patient have?**
Prior osteoporosis related fracture
Secondary cause associated with high risk of fracture such as chronic glucocorticoid use or total immobilization

Or
10-year probability of hip fracture ≥ 3% or a 10-year probability of any major osteoporosis-related fracture ≥ 20% based on the US adapted WHO algorithm in a previously untreated patient

**Treat secondary cause**

No

Repeat DXA yearly if patient on chronic steroids
or Repeat DXA every 2 years if patient not on chronic steroids

No significant change or improved

No

BMD (T-score) < -2.5 SD

Refer to page 7

New fragility fracture of hip, vertebral (clinical or morphometric) or wrist

Refer to page 8

Yes

Refer to page 8
BMD (T-score) < - 2.5 SD

Workup for secondary cause of low BMD
Refer to page 16

Was secondary cause present?

No

Treat secondary cause

Refer to page 8

Yes

Refer to page 8

Refer to page 2
History of fragility fracture of hip, vertebral body or wrist

- DXA Scan if not already done
- Work up for secondary cause of low BMD Refer to page 18
- Refer to page 2

Was secondary cause present?

- No
- Yes

Treat secondary cause

Refer to page 8
Obtain baseline urinary NTx if not already done
Treat with raloxifene, bisphosphonate or denosumab
Refer to page 9 for treatment decision making

Patient of raloxifene or bisphosphonate

Repeat urinary NTx in 3-6 months

Did NTx decrease by at least 30%?

No

Yes

Is the patient taking oral medication to treat osteoporosis correctly?

No

Instruct patient as to how to take medications properly or consider switching patient to IV bisphosphonate or denosumab

Yes

Refer to page 15

New fragility fracture?

No

Repeat urinary NTx yearly

Urinary NTx increased from last NTx

NTx NOT increased from last NTx

Repeat DXA yearly if patient on chronic steroids or Repeat DXA every 2 years if patient not on chronic steroids

No significant changes in BMD or improved

Significant worsening BMD

New fragility fracture

Yes

No

Refer to page 11

Consider switching patient to teraparatide Refer to page 20

Patient on IV bisphosphonate or denosumab?
Is there a history of active malignancy, severe congestive heart failure, active or past history of venous thromboembolic events, including superficial or deep vein thrombosis, pulmonary embolism, retinal vein thrombosis, atrial fibrillation, history of stroke or TIA.

No

Is patient at high risk for the development of invasive breast cancer based on Gail Score?
Refer to page 25

Yes

Treat with Raloxifene
(Use with caution in patients with hepatic impairment and/or moderate to severe renal impairment)

No

Refer to page 10

Is there a history of abnormalities of esophageal emptying such as stricture or achalasia or patient unable to stand or sit upright for 30 minutes, or patient has hypocalcemia?

Yes

Does patient have calculated Crcl* < 30 ml/min

No

Does patient have calculated Crcl* > 35 ml/min

Yes

Treat with Teriparatide
Refer to page 20
or IV ibandronate
Refer to pages 21, 22 and 23 or denosumab

No

Treat with oral Bisphosphonate or Teriparatide -Refer to Page 20 or IV ibandronate-Refer to pages 21, 22 and 23 or IV Zoledronic acid -Refer to Page 24 or denosumab

Yes

Treat with Teriparatide -Refer to page 20 or IV ibandronate
Refer to pages 21, 22 and 23 or IV Zoledronic acid
Refer to page 24 or denosumab

New fragility fracture?

Refer to page 14

No

Yes

Refer to page 15

* Creatinine Clearance (Crcl) measured using Cockcroft and Gault equation
Is there a history of abnormalities of esophageal emptying such as stricture or achalasia or patient unable to stand or sit upright for 30 minutes, or patient has hypocalcemia?

No

Does patient have calculated Crcl* < 30 ml/min

Yes

Does patient have calculated Crcl* < 30 ml/min

No

Treat with Raloxifene or denosumab
(Use with caution in patients with hepatic impairment and/or moderate to severe renal impairment)

No

Treat with Teriparatide
Refer to Page 20 or IV ibandronate
Refer to Pages 21, 22 and 23 or denosumab

Yes

Does patient have calculated Crcl* > 35 ml/min

No

Treat with oral Bisphosphonate or Teriparatide
Refer to page 20 or IV ibandronate
Refer to pages 21, 22 and 23 or IV Zoledronic acid
Refer to page 24 or Denosumab

No

Treat with Teriparatide
Refer to page 20 or IV ibandronate
Refer to pages 21, 22 and 23 or IV Zoledronic acid
Refer to page 24 or Denosumab

Yes

New fragility fracture

No

Refer to page 14

Yes

Refer to page 15

* Creatinine Clearance (Crcl) measured using Cockcroft and Gault equation
New fragility fracture or BMD worse

Consider re-evaluating patient for secondary cause of low BMD
Refer to Page 18

Secondary cause not present
Secondary cause present
Treat secondary cause

Is patient on new medication which could lower BMD?
Refer to page 14 for list of medications

No
Yes

Can patient stop medication?

No
Yes

Determine if patient is taking oral medication to treat osteoporosis correctly

Physician to re-evaluate the patient

Stop medication

Refer to page 12
Patient taking medication correctly

Is patient a candidate for Teriparatide?
Refer to page 20

Yes

Begin Teriparatide

No

Physician to re-evaluate patient

Patient not taking medication correctly

Instruct patient on how to take medications properly

Re-evaluate patient in 3 months to determine if medication being taken correctly

Not taking correctly

Taking correctly

Does patient have calculated Crcl <30ml/mm

Yes

Treat with denosumab

No

Does patient have a calculated Crcl <35ml

No

Treat with Teriparatide
Refer to page 20
or
IV ibandronate
Refer to pages 21, 22 and 23
or
IV Zoledronic acid
Refer to page 24
or
Denosumab

Yes

Treat with Teriparatide
Refer to page 20
or
IV ibandronate
Refer to pages 21, 22 and 23
or
Denosumab

Repeat DXA scan yearly if patient on chronic steroids
or
Repeat DXA every 2 years if patient not on chronic steroids

Refer to page 11

New fragility fracture

No

Refer to page 14

Yes

Refer to page 15
Consider switching to IV bisphosphonate or teriparatide or denosumab

Does patient have a calculated Crcl <30ml/mm

Yes

Treat with denosumab

No

Does patient have a calculated Crcl >35ml/mm

No

Treat with Teriparatide
Refer to page 20 or IV ibandronate
Refer to pages 21, 22 and 23 or Denosumab

Yes

Treat with Teriparatide
Refer to page 20 or IV ibandronate
Refer to pages 21, 22 and 23 or IV Zoledronic acid Refer to page 24 or Denosumab

New fragility fracture

No

Refer to page 14

Yes

Refer to page 15
Follow up DXA Scan

Repeat DXA scan yearly if patient on chronic steroids or Repeat DXA scan every 2 years if patient not on chronic steroids

No significant decrease in BMD

Significant decrease in BMD

Consider re-evaluating patient for secondary cause of low BMD Refer to Page 17

Secondary cause not present

Secondary cause present

Treat secondary cause

Is patient on new medication which could lower BMD? Refer to page 16 for list of medications

No

Is patient on oral or IV bisphosphonate or denosumab?

Yes

Consider switching patient to teriparatide Refer to page 20

No

Can patient stop medication?

Yes

Stop medication

No

Physician to re-evaluate patient
New fragility fracture

Consider re-evaluating patient for secondary cause of low BMD
Refer to page 17

Secondary cause not present

Secondary cause present

Treat secondary cause

Is patient on new medication which could lower BMD?
Refer to page 16 for list of medications

No

Yes

Is patient on oral or IV bisphosphonate or denosumab?

Can patient stop medication?

No

Yes

Consider switching patient to teriparatide
Refer to page 20

Stop medication

Physician to re-evaluate patient
RISK FACTORS FOR OSTEOPOROSIS

GENETIC FACTORS:
- Family history of osteoporosis
- First-degree relative with osteoporosis related fracture
- Caucasian or Asian

ENVIRONMENTAL FACTORS:
- Cigarette smoking
- Alcohol abuse
- Physical inactivity
- Thin habitus
- Tallness
- Diet low in calcium
- Vitamin D deficiency
- Little exposure to sunlight
- Malnutrition
- Prolonged breast feeding
- Excessive ingestion of caffeine
- Increased likelihood of falling

MENSTRUAL STATUS:
- Early menopause (before the age of 45 years)
- Prolonged secondary amenorrhea (e.g. due to anorexia, nervosa, hyperprolactinemia or women athletes)

DRUG THERAPY:
- Glucocorticoids (>5mg/day of Prednisone or its equivalent for > 3 months)
- Antiepileptic drugs (e.g. phenytoin)
- Chemotherapy
- Chronic phosphate-binding antacid use
- Excessive substitution therapy (e.g. Thyroxine and Hydrocortisone)
- Lithium
- Methotrexate (chemotherapy doses)
- Anticoagulant drugs (e.g. heparin > 6 months)
- Immuno suppressive therapy (cyclosporine at transplant doses)
- Gonadotropin releasing hormone antagonists

ENDOCRINE DISEASES
- Primary hyperparathyroidism
- Hyperthyroidism
- Type I diabetes mellitus
- Cushing’s Syndrome
- Addison’s disease
- Hypogonadism
- Anorexia nervosa
- Acromegaly
HEMATOLOGIC DISEASES
  Multiple myeloma
  Systemic mastocytosis
  Lymphoma, leukemia
  Pernicious anemia
  Sickle cell disease
  Thalassemia

RHEUMATOLOGIC DISEASES
  Rheumatoid arthritis
  Ankylosing spondylitis
  Scleroderma
  Systemic lupus erythematosus

PULMONARY DISEASES
  COPD

GASTROINTESTINAL DISEASES
  Malabsorption syndromes (e.g. celiac disease, Crohn’s disease, gastric by pass, or surgery
  for peptic ulcer disease)
  Chronic liver disease (e.g. primary biliary cirrhosis)

RENAL DISEASE
  Chronic renal failure
  Hypercalcuria
  Renal tubular acidosis or disorders of collagen metabolism

BONE DISEASES
  Radiographic evidence of vertebrae deformity and/or osteopenia/osteoporosis
  Previous fragility fractures (vertebral, hip, or wrist)
  Osteogenesis imperfecta
  Homocystinuria due to cystathionine deficiency
  Ehlers-Danlos syndrome
  Marfan’s syndrome

OTHER DISEASES
  Sarcoidosis
  Porphyria
  Hypophosphatasia in adults
LOW BMD WORKUP

Patient’s Name: ___________________________ D.O.B.: ______________

ORDER THE FOLLOWING TESTS IF NOT DONE IN THE LAST 6 MONTHS:

* CBC
Serum Calcium
Phosphorus
*TSH Reflex
25 Hydroxyvitamin D Level
Intact PTH Level (Draw 8am-10am)
Spot Urinary N-telopeptide (NTx)
(Obtain from second voided urine specimen between 8am-10am)
Spot urine for calcium/creatinine ratio
8 AM Total Testosterone (Male)
SEP/UPEP if patient has had osteoporotic fracture
All of the above studies

Ordered By: _____________________________

Date Ordered: ___________________________

* Patient needs to sign a waiver since Medicare does not cover CBC and TSH.
Dosages of TUMS and Citracal

<table>
<thead>
<tr>
<th>Total Daily CALCIUM Required</th>
<th>TUMS Regular 200 mg calcium each</th>
<th>TUMS E-X 300 mg calcium each</th>
<th>TUMS Ultra 400 mg calcium each</th>
<th>TUMS 500 500 mg calcium each</th>
<th>Citracal Maximum 315 mg/Caplet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teens &amp; Young Adults (1200 mg)</td>
<td>6 Tablets</td>
<td>4 Tablets</td>
<td>3 Tablets</td>
<td>3 Tablets</td>
<td>4 Tablets</td>
</tr>
<tr>
<td>Adults 25-50 (1000 mg)</td>
<td>5 Tablets</td>
<td>4 Tablets</td>
<td>3 Tablets</td>
<td>2 Tablets</td>
<td>3 Tablets</td>
</tr>
<tr>
<td>For maintenance of pre-menstrual balance (1200 mg)</td>
<td>6 Tablets</td>
<td>4 Tablets</td>
<td>3 Tablets</td>
<td>3 Tablets</td>
<td>4 Tablets</td>
</tr>
<tr>
<td>Pregnant or lactating women (1200 mg)</td>
<td>6 Tablets</td>
<td>4 Tablets</td>
<td>3 Tablets</td>
<td>3 Tablets</td>
<td>4 Tablets</td>
</tr>
<tr>
<td>Postmenopausal women on estrogen (1000 mg)</td>
<td>5 Tablets</td>
<td>4 Tablets</td>
<td>3 Tablets</td>
<td>2 Tablets</td>
<td>3 Tablets</td>
</tr>
<tr>
<td>Postmenopausal women not on estrogen (1500 mg)</td>
<td>8 Tablets</td>
<td>5 Tablets</td>
<td>4 Tablets</td>
<td>3 Tablets</td>
<td>5 Tablets</td>
</tr>
</tbody>
</table>
Forteo (Teriparatide) Worksheet and Patient Referral to Pharmacists’ Osteoporosis Clinic

Patient Name _______________________________  DOB  _______________________
SS#  _______________________________________ Date  ________________________

* Y e s   N o

1. Calculated GFR < 30 ml/min
   ☐ ☐

2. History of radiation therapy to the skeleton
   ☐ ☐

3. History of cancer of or metastatic to the bone
   ☐ ☐

4. Elevated PTH level
   (PTH level _____ Upper limit of normal level is _______ )
   ☐ ☐

5. Elevated serum calcium
   (Serum calcium level _____  Upper limit of normal level is _____ )
   ☐ ☐

6. History of Paget’s Disease of the bone
   ☐ ☐

7. Elevated serum alkaline phosphatase Level of ________
   (Upper limit of normal level is _____) with normal GGT Level _____ (Upper limit of normal level is _____)
   and Bone Scan and/or x-rays of bone compatible with Paget’s Disease
   ☐ ☐

8. Metabolic bone disease other than osteoporosis
   ☐ ☐

*Order alkaline phosphatase and GGT. If alkaline phosphatase is elevated and GGT is normal, order total body bone scan. Reason: “Unexplained elevation of alkaline phosphatase, rule out Paget’s Disease.”

*Any “yes” answer indicates that the patient has contraindications to Forteo and should NOT TAKE IT.

If patient is a candidate for Forteo (Teriparatide) (answers “no” to all above questions) and is currently an inpatient, please assess patient’s cognitive ability to be educated before discharge.

Is the patient able to learn about Forteo and proper injection technique before discharge from the hospital?

Yes  ☐  No  ☐

Signature of person completing this worksheet

Name of physician authorizing referral __________________________________________________________________________
Signature of physician/Date __________________________________________________________________________

Please fax form to Lynn Bailey or Angie Pennington in Dr. Kelling’s office for insurance purposes: 704-783-1090.
Boniva (ibandronate sodium) Injection
Key Points

- 3mg/3ml for intravenous therapy administered over a period of 15-30 seconds every 3 months.
- Boniva is supplied in pre-filled syringes with butterfly attached.
- Do not mix with any other drugs.
- If dosage is missed, it should be rescheduled as soon as possible and then every 3 months. Do not administer more frequently.
- Adverse side effects similar to oral Boniva.
- A serum creatinine must be obtained with 48 hours prior to each administration. Verify calcium duo within 12 months.
- For coding purposes, patient must have diagnosis of 733.01 or 733.09. Must also have documented secondary diagnosis of intolerance to oral therapy (995.27).
- Must be administered by a nurse and vital signs should be obtained prior to injection.
- Patients should remain in lobby for 30 minutes post injection.
- Communicate to patient the importance of having good dental hygiene and annual checkups with dentist.
  Also, patients may experience some flu-like symptoms after the first injection.
SUBJECT:
Intravenous Boniva

POLICY STATEMENT:
Define the process for eligibility and administration of intravenous Boniva.

POLICY:

Eligibility
1. Patient must meet the following criteria prior to being considered for IV Boniva:
   a. Have diagnosis of 733.01 senile osteoporosis (postmenopausal osteoporosis) or 733.09 (osteoporosis specific type NEC)
   b. Must have documentation of intolerance to oral therapy and/or inability to take oral therapy (995.27).
2. CIPM staff will then contact the BONIVA Reimbursement Hotline at 1-888-587-9438 to determine eligibility, providing the patients name and DOB. BONIVA will then fax us a form to complete and obtain patient authorization. If patient is unavailable, they will accept an on file HIPPA consent.
3. Once form is completed, fax back to BONIVA and await eligibility status. Once completed, they will follow up with a fax to include eligibility determination and the amount of the co-pay that we will collect.
4. Patient should then be contacted.

Administration
1. Once eligibility has been determined and patient is aware of their financial responsibility if applicable, an injection appointment should be made for the patient and serum creatinine obtained with in 48 hours of administration. If patient has not had a baseline calcium duo, then it should be ordered.
2. At the time of the visit, vital signs should be obtained and confirmation of labs. Boniva should not be given if creatinine clearance is < 30ml/min.
3. Boniva should be ordered from the pharmacy upon patient arrival and administered accordingly (3mg/3ml over 15-30 seconds, given every 3 months). See attached key points
**BONIVA Log**  
(Injection given every 3 months)

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Diagnosis:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>SS#:</th>
<th>Date of Birth:</th>
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<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>*Creatinine</th>
<th>Creatinine Clearance (GFR)</th>
<th>Date of last Ca Duo (yearly)</th>
<th>*BP/Pulse/Resp</th>
<th>*Weight</th>
<th>IV site</th>
<th>Side Effects (Y or N) if yes document in Notes &amp; make Provider aware</th>
<th>Nurse Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

*Document in TouchWorks

**Creatinine must be obtained prior to each injection**  
Order STAT creatinine within 48 hours of each injection  
Boniva should not be given if creatinine clearance (GFR) is <30ml/min.

Follow up labs: Due Date

<table>
<thead>
<tr>
<th>Creatinine</th>
<th>Ca Duo</th>
</tr>
</thead>
<tbody>
<tr>
<td>______</td>
<td>______</td>
</tr>
</tbody>
</table>

**ORDERS**

- [ ] Initiate intravenous Boniva per protocol every 3 months  
- [ ] D/C Boniva

<table>
<thead>
<tr>
<th>MD Signature</th>
<th>MD Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<table>
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<th>Date</th>
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**PATIENT INFORMATION**

<table>
<thead>
<tr>
<th>Name</th>
<th>DOB</th>
<th>SS#</th>
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<tbody>
<tr>
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<td></td>
</tr>
<tr>
<td>City</td>
<td>State</td>
<td>Zip</td>
</tr>
</tbody>
</table>

**Diagnosis (ICD-9):** 733.00  731.00

**Gender:** Male  Female

**PATIENT INSURANCE INFORMATION**

<table>
<thead>
<tr>
<th>Primary Insurance</th>
<th>Secondary Insurance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company Name:</td>
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<td>Phone:</td>
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**Policy #**  **Group**  **Policy #**  **Group**

**POLICY HOLDER INFORMATION**

<table>
<thead>
<tr>
<th>Name</th>
<th>Employer</th>
<th>SS #:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td></td>
<td></td>
</tr>
<tr>
<td>City</td>
<td>State</td>
<td>Zip</td>
</tr>
</tbody>
</table>

**Relationship to Patient**

**Benefit Verification Requires ICD-9:** Please select only one

**Referring Provider**  **Infusing Provider**  **Site of Service**

**REFERRING PROVIDER INFORMATION** (if you are not infusing, Infusing Provider or Site of Service section must also be completed)

<table>
<thead>
<tr>
<th>Name</th>
<th>NPI #</th>
<th>Tax ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>Phone</td>
<td>Fax</td>
</tr>
<tr>
<td>City</td>
<td>State</td>
<td>Zip</td>
</tr>
</tbody>
</table>

**INFUSING PROVIDER INFORMATION** (Complete if infusing in MD, Office)

<table>
<thead>
<tr>
<th>Name</th>
<th>NPI #</th>
<th>Tax ID #</th>
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<tbody>
<tr>
<td>Site Name</td>
<td>DEAR #</td>
<td>Payor Specific ID #</td>
</tr>
<tr>
<td>Address</td>
<td>Phone</td>
<td>Fax</td>
</tr>
<tr>
<td>City</td>
<td>State</td>
<td>Zip</td>
</tr>
</tbody>
</table>

**Site of Service** (Complete if infusing in Hospital/Outpatient, Infusion Center or LTC)

<table>
<thead>
<tr>
<th>Site Name</th>
<th>NPI #</th>
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</thead>
<tbody>
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</tr>
<tr>
<td>City</td>
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**PLEASE FILL OUT THE INFORMATION ABOVE, SIGN THE FORM AND RETURN BY FAX OR MAIL.**

**Physician Consent for Benefit Investigation:** I authorize the Reclast Reimbursement Hotline to obtain information from my patient's insurance company to verify benefit for Reclast. By signing below, you are indicating you have the patient's written consent to release this information on file.

**Physician Representative Signature:**  
**Date:**

**Patient Consent:** I understand my information will be used solely for the purposes of verification of insurance coverage, alternative coverage research and eligibility for the program and will not be shared for any other purposes. I authorize the Reclast Reimbursement Hotline to obtain information from my physician, insurance company, and other sources as deemed necessary to ensure the accuracy and completeness of understanding my coverage for Reclast. I understand that information regarding my insurance coverage will be shared with my physician and agents of Novartis Pharmaceuticals Corporation who administers the Reclast Reimbursement Hotline and/or the Reclast Patient Assistance Program for treatment purposes.

[ ] Yes, it is ok to leave a message with someone else in my household and/or on my answering machine  
[ ] No, do not leave messages

**Patient Signature:**  
**Date:**

**FINANCIAL INFORMATION (ONLY COMPLETE IF APPLYING FOR PATIENT ASSISTANCE PROGRAM)** Financial information is required including proof of income to apply for patient assistance. Patient will be asked for the following:

- Current tax returns
- Bank statements
- Pay stubs or Social Security Award letter

<table>
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<th>Household Size:</th>
<th>Annual Income:</th>
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**NOVARTIS**

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East Hanover, NJ 07936  
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4.16.08 Reclast Physician Reminder Letter.doc  
SiteID-ProvID:3,873.00-3,820
GAIL MODEL – Staff Worksheet
BREAST CANCER RISK ASSESSMENT TOOL

Patient______________________________   D.O.B._________________

Pt answers:
1. Have you ever had breast cancer? Y N
2. How old are you? ________________
3. What was your age at the time of your first menstrual period? ________________
   If you don’t know check here ________  *age 12 is the default*
4. How old were you when you first gave birth to a child (live birth)? ________________
   If never check here ________________
5. How many of your first degree relatives (mother, sister, daughter) have had breast cancer? ________________
6. Have you ever had a breast biopsy? Y N
   a. How many breast biopsies have you had? ________________
   b. Were any of the biopsies positive for breast cancer? Y N
7. What your race/ethnicity?  Circle one:  Black/African American  White  Hispanic/Latina  Asian or Pacific Islander  American Indian or Alaska Native

For pt information you can reinforce:
Based on the information you have given us we will calculate a risk score for breast cancer. If you are at high risk your medical provider will discuss this and if a medicine may be a good idea for you to reduce your risk.

FYI:
Possible contraindications to the medicine (Raloxifene) include history of TIA, CVA, or DVT. It is not recommended for premenopausal women.
Check date and remind provider to order mammogram if due?
Go to http://www.cancer.gov/bcrisktool and calculate risk based on above info.

5 year risk based on Gail Model is __________ 1.67% or above is cutoff for response.

Provider response:
  __discussed at visit today see note. __________________________________________
  __bring patient in for separate visit to discuss: scheduled ______________________

Notify pt “score sheet you did shows you may benefit from a medicine to help prevent breast cancer in the future and the provider would like to discuss this with you”
  __score considered but risks of treatment may outweigh benefit in this pt, not recommended

Date _____________________  Provider signature___________________________
bar foot or wearing slippers.

- Wearer shoes both inside and
  outside the house. Avoid going
  barefoot or wearing slippers.

- Have all medications and glasses
  within easy reach.

- Use non-slip mats in the bath
  and on shower floors.

- Use a step stool when washing.

- Keep items you use often in
  reach.

- Have grab bars in the next 4.

- Keep items you use often in
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