Clinical Policy Title: Agents for osteoporosis

Clinical Policy Number: 00.02.05

Effective Date: March 1, 2014
Initial Review Date: December 18, 2013
Most Recent Review Date: January 18, 2017
Next Review Date: January 2018

Related policies:

CP # 236.200 PerformRx Injectable-Infusible Osteoporosis Agents
CP # 17.01.01 Bone mineral density measurement

ABOUT THIS POLICY: AmeriHealth Caritas Northeast has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Northeast’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas Northeast when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Northeast’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Northeast’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Northeast will update its clinical policies as necessary. AmeriHealth Caritas Northeast’s clinical policies are not guarantees of payment.

Coverage Policy

AmeriHealth Caritas Northeast considers the use of the following Infusible agents for treatment of postmenopausal osteoporosis to be clinically proven and therefore, medically necessary:

- BONIVA INJECTION® (ibandronate sodium): 3 mg/3mL single use syringe
- FORTEO® (teriparatide [rDNA origin] injection): 20mcg/dose in a 2.4ml prefilled pen
- PROLIA™ (denosumab): 60 mg/1mL
- RECLAST® (zoledronic acid): 5 mg/100mL

DOSAGE AND ADMINISTRATION:

Boniva - Osteoporosis in Postmenopausal Women: 3 mg IV given once every 3 months

Forteo - Osteoporosis in Postmenopausal Women/Men & Treatment and Prevention of Glucocorticoid-Induced Osteoporosis: 20 mcg once a day administered as a subcutaneous injection into the thigh or abdominal wall. The length of therapy should be no longer than two years.
**Prolia - Osteoporosis in Men & Postmenopausal Women, Bone Loss in Men receiving Androgen Deprivation Therapy for Prostate Cancer & Bone Loss in Women Receiving Adjuvant Aromatase Inhibitor Therapy for Breast Cancer:** 60 mg administered as a single subcutaneous injection once every 6 months administered via subcutaneous injection in the upper arm, the upper thigh, or the abdomen. All patients should receive calcium 1000 mg daily and at least 400 IU vitamin D daily.

**Reclast - Treatment of Postmenopausal Osteoporosis/ Osteoporosis in Men & the Treatment and Prevention of Glucocorticoid-Induced Osteoporosis:** 5 mg infusion once a year given intravenously over no less than 15 minutes. Patients must be adequately supplemented with calcium and vitamin D if dietary intake is not sufficient. All patients should receive at least 1200 mg of calcium and 800-1000 IU of vitamin D daily.

**Prevention of Osteoporosis in Postmenopausal Women:** a 5 mg infusion given once every 2 years intravenously over no less than 15 minutes. Patients must be adequately supplemented with calcium and vitamin D if dietary intake is not sufficient. Postmenopausal women require an average of 1200 mg calcium and 800-1000IU vitamin D daily;

**Paget’s Disease of the Bone:** a 5 mg infusion. The infusion must be given over a constant infusion rate of no less than 15 minutes.

**Limitations:**

All other uses of Ibandronate (Boniva) and Zoledronic acid (Reclast, Zometa) are not medically necessary. AmeriHealth Caritas Northeast covers the above medications for the prevention and treatment of Osteoporosis. Zoledronic Acid (ZA) (Reclast) is a bisphosphonate drug that was developed initially for treatment of postmenopausal osteoporosis; however, it is currently being evaluated for treatment of bone loss due to other causes.

**Alternative Covered Services:**

A. Medications approved for Osteoporosis that are prescribed not by infusion but by other routes:
   1. Alendronate Sodium or Alendronate Sodium plus Vitamin D3 (Fosamax®/Fosamax Plus D)-Tablet.
   2. Ibandronate 150 mg tablet.
   3. Risedronate Sodium or Risedronate Sodium with Calcium Carbonate (Actonel®, Actonel® with Calcium and Atelvia™) - Tablet.
   4. Calcitonin-Salmon (Fortical® and Miacalcin®) - Nasal Spray.
   5. Denosumab (Prolia) - Injection.
   6. Raloxifene (Evista®) – Tablet.
   7. Teriparatide Parathyroid Hormone (PTH) (1-34) (Forteo®) - Self-administer injection.
   8. Estrogen Therapy (ET) and Hormone Therapy (HT) (Multiple brands available) - tablet or skin (transdermal) patch.
**Bisphosphonates:** Several bisphosphonates are approved for the prevention or treatment of osteoporosis. These medications reduce the activity of cells that cause bone loss.

**Parathyroid hormone:** A form of human parathyroid hormone (PTH) is approved for postmenopausal women and men with osteoporosis who are at high risk for having a fracture. Use of the drug for more than 2 years is not recommended.

**RANK ligand (RANKL) inhibitor:** A RANK ligand (RANKL) inhibitor is approved for postmenopausal women with osteoporosis who are at high risk for fracture.

**Estrogen agonists/antagonists:** An estrogen agonist/antagonist (also called a selective estrogen receptor modulator or SERM) is approved for the prevention and treatment of osteoporosis in postmenopausal women. SERMs are not estrogens, but they have estrogen-like effects on some tissues and estrogen-blocking effects on other tissues.

**Calcitonin:** Calcitonin is approved for the treatment of osteoporosis in women who are at least 5 years beyond menopause. Calcitonin is a hormone involved in calcium regulation and bone metabolism.

**Estrogen and hormone therapy:** Estrogen and combined estrogen and progestin (hormone therapy) are approved for the prevention of postmenopausal osteoporosis as well as the treatment of moderate to severe hot flashes and vaginal dryness that may accompany menopause. Estrogen without an added progestin is recommended only for women who have had a hysterectomy (surgery to remove the uterus), because estrogen increases the risk of developing cancer of the uterine lining and progestin reduces that risk.

**Background**

Osteoporosis is a progressive bone disease characterized by a decrease in bone mass and density which can lead to an increased risk of fracture. In osteoporosis, the bone mineral density (BMD) is reduced, bone microarchitecture deteriorates, and the amount and variety of proteins in bone are altered. Osteoporosis is defined by the World Health Organization (WHO) as a basis for assessing fracture risk in screening. The definition, based on recommendations of expert panels convened in 1994 and 2008, combines bone mineral density (T-score) and history of a fracture (4BoneHealth, 2016).

In the United States, of 99 million persons age 50 and older, over half have either osteoporosis or low bone mass. A total of 10.2 million had osteoporosis, while another 43.4 million had low bone mass in 2010. Women represented 80 percent (8.2 million) of persons with osteoporosis and 63 percent (27.3 million) of men with low bone mass. The total of over 53.6 million Americans over age 50 with either disorder in 2010 is expected to rise to over 70 million by 2030. Non-Hispanic whites had the highest rate of these conditions, while non-Hispanic blacks had the lowest (Wright, 2014).
The form of osteoporosis most common in women after menopause is referred to as primary type 1 or postmenopausal osteoporosis. Primary type 2 osteoporosis or senile osteoporosis occurs after age 75 and is seen in females and males at a ratio of 2:1. Secondary osteoporosis may arise at any age and affect men and women equally. This form results from chronic predisposing medical problems or disease or prolonged use of medications such as glucocorticoids, when the disease is called steroid-or glucocorticoid induced osteoporosis.

Perhaps the greatest threat posed by osteoporosis is the elevated risk of fractures. Over 80 percent of fractures in persons over age 50 are caused by osteoporosis. Hip fractures are among the most common types of fractures in the elderly; they are not only costly, but hazardous; 28 percent of women and 37 percent of men who suffer hip fractures will live less than one year (Osteoporosis Canada, 2016).

Effective diagnosis and treatment of osteoporosis can prevent millions of fractures and the pain and disability that follow them. However, many fractures still occur despite preventive efforts. For fragile patients with severe osteoporosis, slowing bone loss with anti-resorptive drugs may be insufficient to protect against fracture. An anabolic agent that increases bone formation can represent a more effective option. Currently, teriparatide is one FDA-approved bone anabolic for treatment of osteoporosis. Screening for osteoporosis is covered under the Patient Protection and Affordable Care Act (ACA) of 2010. For persons with a new insurance plan starting September 23, 2010, this screening is covered without a co-payment or co-insurance to meet a deductible (HHS, 2010). A number of states have enacted laws addressing education, public awareness, and prevention of osteoporosis; some mandate insurance coverage for osteoporosis-related diagnostic and treatment services.

A 2012 guideline from the Endocrine Society sets recommendations for initial screening (using dual energy X-ray and absorbiometry) and follow-up of bone mineral density in males over 50, and also states that pharmacological therapy is indicated for those with low density or other risk factors for fracture (Watts, 2012). The U.S. Preventive Services Task Force cited evidence that drug therapy reduces fracture risk in elderly women, as part of its guideline on screening (USPSTF, 2011).

Although there is no cure for osteoporosis, it is treatable and preventable. Several medications are available to help stop or slow bone loss, to help form new bone, and to reduce the risk of fractures. Among the non-nitrogen-containing bisphosphonates, there are three main alternatives – clodronate, etidronate, and tiludronate. Among the nitrogen-containing bisphosphonates, aside from ibandronate, there are six basic alternatives – alendronate, neridronate, olpadronate, pamidronate, risedronate, and zoledronate. The bisphosphonates available in an IV formulation include ibandronate, pamidronate, and zoledronate. However, only ibandronate IV is approved for the treatment of postmenopausal osteoporosis; the other IV formulations are used for the treatment of cancer patients. Other clinical alternatives include the following: calcium and vitamin D supplementation; calcitonin, a naturally occurring hormone involved in calcium regulation and bone metabolism; estrogen/progestin therapy; raloxifene, a selective estrogen receptor modulator; teriparatide, an injectable form of human parathyroid hormone; and combination therapy.
Searches

AmeriHealth Caritas Northeast searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

Searches were conducted on November 30, 2016 using the terms “Osteoporosis” and “bisphosphonates.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

Few studies have compared efficacy of medications for osteoporosis against each other. The Agency for Healthcare Research and Quality (AHRQ) reports that alendronate, risendronate, zoledronic acid, denosumab, and teriparatide reduce risk of vertebral and non-vertebral fractures among postmenopausal women with the disorder. The same drugs (minus teriparatide) also show significant results in preventing hip fractures among postmenopausal women with osteoporosis (Crandall, 2012).

Findings to date have found all bisphosphonates to be effective in reducing fracture risk, with zoledronic acid typically cited as most effective. These studies include:

- A meta-analysis of nine controlled trials with 2464 men with osteoporosis found that compared to placebo, bisphosphonates reduced risk of vertebral and non-vertebral fracture by 64 and 48 percent, respectively (Chen, 2015a).
- Guidelines published by the French National Authority for Health in 2012 recommended pharmacotherapy for women with a history of severe osteoporotic fracture, with zoledronic acid as the preferred first-line medication after a hip fracture (Briot, 2012).
- In a meta-analysis of eight placebo-controlled trials, zoledronic acid also was found to be more effective than four other drug therapies in reducing vertebral, non-vertebral, and hip fractures among postmenopausal women with osteoporosis (Jansen, 2011).
- A meta-analysis of ten trials ranked zolendronic acid as most effective in preventing vertebral fracture in primary osteoporosis, while risedronate was most effective in preventing fractures in primary and corticosteroid-induced osteoporosis (Zhou, 2016a).
A meta-analysis of 36 studies of persons taking a bisphosphonate for primary osteoporosis documented that all seven drugs caused significant decreases in fracture risk compared to placebo, with zolendronic acid having the greatest decrease (Zhou, 2016b).

A systematic review of 30 studies including 59,209 post-menopausal women taking one of nine drugs assessed fracture rates, including vertebral, non-vertebral, hip and wrist fractures. Teroparatide, zoledronic acid, and denosumab demonstrated the greatest efficacy in preventing non-vertebral and vertebral fractures (Hopkins, 2011).

Other studies of osteoporosis drug efficacy have focused on outcomes other than fracture risk. A meta-analysis of 13 studies and 3647 men with osteoporosis taking one of eight drugs (compared to placebo) documented that each drug improved bone mass density (BMD), and that zolendronate was the most effective (Chen, 2015a).

A meta-analysis assessed four studies and 3088 patients with osteoporosis and a fracture, randomized to taking a bisphosphonate and controls. It found that bisphosphonates caused significant reductions in second hip fractures (40 percent, n=33) and mortality (34 percent, n=122), compared to controls. The overall complication rate in elderly persons taking a bisphosphonate was not increased (Peng, 2016).

A meta-analysis showed the efficacy of bisphosphonates on reducing bone-specific alkaline phosphatase and C-terminal telopeptide of type I collagen, and increasing bone marrow density (Chen, 2015b).

A meta-analysis of 34 studies and 11,090 subjects with osteoporosis and BMD treated with ibandronate assessed measures of improvement. The study identified that longer treatment duration (1-5 years), increasing age, lower baseline T scores, and higher serum CTX levels were the predictors of the greatest improvements in patient health status (Ma, 2016).

While osteoporosis is rare in children and adolescents, bisphosphonate therapy is considered the pharmacological treatment of choice (Saraff, 2015). Few studies have evaluated efficacy of this treatment in pediatric populations. One review of 281 children in nine studies found three fractures in those taking a bisphosphonate, versus six in the control group (Ward, 2007). A study of adolescents and young adults (age 10-45) enrolled in a large health insurance company reported the number of bisphosphonates initiators decreased from 1,670 to 344 between 2004 and 2012; authors speculate that growing concerns over side effects may be the cause of this trend (Xie, 2015).

The 2012 AHRQ review also noted that adherence to drug therapy for osteoporosis is poor, due to dosing frequency, side effects, knowledge of osteoporosis, and cost (Crandall, 2012). A systematic review found that over a one-year period, adherence to bisphosphonates in males with osteoporosis ranged from 32 to 64 percent, posing a barrier to improving outcomes (Mikyas, 2014). Patients are much more likely to prefer annual zoledronic acid infusions (66.4-78.8 percent) over weekly bisphosphonates (9.0-19.7 percent) (Lee, 2011).
Studies of cost effectiveness of bisphosphonates for osteoporosis have been conducted. One study from Switzerland, consistent with other European studies, found treatment with oral bisphosphonates in women over age 70 with osteoporosis or at least one fracture risk is cost effective relative to no treatment. Results are most affected with changes in fracture risk, cost of fractures, cost of treatment, nursing home admissions, and adherence to treatment (Lippuner, 2011).

There may be disparities among utilization and outcomes for persons with osteoporosis. One study of 48,390 women over age 50 in northern California taking bisphosphonate therapy and tracked for an average of 7.7 years documented fracture risk was eight-fold higher for Asian women than for white women (64.2 vs. 7.6 fractures per 100,000). Asian women also were treated an average of 3.8 years, significantly greater than the 2.7 figure for white women (Lo, 2016).

Policy Updates:

The December 2016 version of this policy contains seven new guidelines/other, along with 16 peer reviewed references, including a number of recent meta-analyses and systematic reviews. A number of general or non-current references have been removed. The background and findings sections have been re-written to reflect these new references, and the summary of clinical evidence section now reflects only the most current and most critical results.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
<th>Key points:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peng (2016)</td>
<td>Efficacy of bisphosphonates for preventing hip fracture and reducing mortality</td>
<td>• Meta-analysis of 4 studies (n=3088), elderly patients with hip fracture</td>
</tr>
<tr>
<td></td>
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<td>• Comparison of patients on bisphosphonate and controls</td>
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<tr>
<td></td>
<td></td>
<td>• Bisphosphonate group had significantly lower mortality (34 percent)</td>
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<tr>
<td></td>
<td></td>
<td>• Bisphosphonate group had significantly lower second hip fractures (40 percent)</td>
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<td></td>
<td></td>
<td>• No difference in overall complication rates between two groups</td>
</tr>
<tr>
<td>Zhou (2016b)</td>
<td>Comparing efficacy of 7 bisphosphonates to reduce fracture risk in primary osteoporosis</td>
<td>• Meta-analysis of 36 studies, persons with primary osteoporosis</td>
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<td></td>
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<td>• Seven drugs significantly reduced chance of vertebral fracture, with zolendronic acid (ZA) showing the greatest reduction</td>
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<td></td>
<td></td>
<td>• Fracture risk in ZA 35% less than alendronate</td>
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<td></td>
<td>• Fracture risk in ZA 47% less than clodronate</td>
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<td>• Fracture risk in ZA 55% less than etidronate</td>
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<td>• Fracture risk in ZA 48% less than ibandronate</td>
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<td></td>
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<td>• Fracture risk in ZA 41% less than risedronate</td>
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<tr>
<td></td>
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<td>• Fracture risk in ZA 69% less than tiludronate</td>
</tr>
<tr>
<td>Ma (2016)</td>
<td><strong>Key points:</strong></td>
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</tbody>
</table>
| Predictors of ibandronate efficacy in subjects with osteoporosis or decreased BMD | • Meta-analysis of 34 studies (n=11,090)  
• Higher ibandronate efficacy predicted for patients with  
  1. Longer duration treatment (1-5 years)  
  2. Increasing age  
  3. History of previous fractures  
  4. Lower baseline T score  
  5. Higher baseline levels of C-terminal telopeptide of type 1 collagen |

<table>
<thead>
<tr>
<th>Chen (2015a)</th>
<th><strong>Key points:</strong></th>
</tr>
</thead>
</table>
| Effectiveness of drugs in improving bone mineral density (BMD) for men with osteoporosis | • Meta-analysis of 13 studies (n=3647) of men with osteoporosis  
• BMD increase for each of eight drugs compared with placebo  
• Used standardized mean differences (SMD) for each drug  
• SMD for zoledronate = 13.48  
• SMD for alendronate = 11.04  
• SMD for teriparatide = 10.98  
• SMD for risedronate = 10.33  
• SMD for teriparatide = 9.33  
• SMD for strontium ranelate = 8.88  
• SMD for ibandronate = 5.49  
• SMD for parathyroid hormone = 4.89  
• SMD for alfacalcidol = 3.42 |

**References**

**Professional society guidelines/other:**


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCD):**


Zoledronic acid- Medicare has determined that providers can no longer bill J3487 (Zometa) and J3488 (Reclast) as of July 2013. They can bill Q2051 (Injection, Zoledronic Acid, Not Otherwise specified, and 1 mg). The LCD for this service is the following:

<table>
<thead>
<tr>
<th>LCD ID</th>
<th>LCD Name</th>
<th>Contractor/State</th>
</tr>
</thead>
<tbody>
<tr>
<td>L30035</td>
<td>Drugs and Biologicals: Zoledronic Acid</td>
<td>Cahaba GBA/Georgia and Tennessee</td>
</tr>
<tr>
<td>L32110</td>
<td>Bisphosphonates (Intravenous [IV]) and Monoclonal Antibodies in the Treatment of Osteoporosis and Their Other Indications</td>
<td>First Coast Service Options/Florida (Part A)</td>
</tr>
<tr>
<td>L32100</td>
<td>Bisphosphonates (Intravenous [IV]) and Monoclonal Antibodies in the Treatment of Osteoporosis and Their Other Indications</td>
<td>First Coast Service Options/Florida (Part B)</td>
</tr>
<tr>
<td>L30139</td>
<td>Bisphosphonate Drug Therapy (only for Paget’s Disease)</td>
<td>Wisconsin Physician Services- Multiple States</td>
</tr>
</tbody>
</table>

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill in accordance with those manuals.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>96374</td>
<td>Therapeutic, prophylactic or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug (List separately in addition to code for primary procedure)</td>
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</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>M80.0</td>
<td>Age-related osteoporosis with pathological fracture without current pathological fracture</td>
<td>Requires a fifth digit to be valid</td>
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<tr>
<td>M80.81</td>
<td>Other osteoporosis with pathological fracture, shoulder</td>
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<tr>
<td>Code</td>
<td>Description</td>
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<tr>
<td>M80.841S</td>
<td>Other osteoporosis with current pathological fracture, right hand, sequela</td>
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<tr>
<td>M80.819S</td>
<td>Other osteoporosis with current pathological fracture, unspecified shoulder, sequel</td>
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<tr>
<td>M80.849A</td>
<td>Other osteoporosis with current pathological fracture, unspecified hand, initial encounter for fracture</td>
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<tr>
<td>M80.812S</td>
<td>Other osteoporosis with current pathological fracture, left shoulder, sequela</td>
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<td>M80.811S</td>
<td>Other osteoporosis with current pathological fracture, right shoulder, sequela</td>
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<tr>
<td>M80.842A</td>
<td>Other osteoporosis with current pathological fracture, left hand, initial encounter for fracture</td>
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<td>M80.841A</td>
<td>Other osteoporosis with current pathological fracture, right hand, initial encounter for fracture</td>
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<td>M80.869S</td>
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<td>M80.852S</td>
<td>Other osteoporosis with current pathological fracture, left femur, sequela</td>
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<td>M80.862S</td>
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<td>M80.861S</td>
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<td>M80.80xS</td>
<td>Other osteoporosis with current pathological fracture, unspecified site, sequela</td>
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<td>M80.819A</td>
<td>Other osteoporosis with current pathological fracture, unspecified shoulder, initial encounter for fracture</td>
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<tr>
<td>M81.0</td>
<td>Age-related osteoporosis without pathological fracture</td>
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<td></td>
<td>Requires a sixth and seventh digit to be valid</td>
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<td>M81.6</td>
<td>Localized osteoporosis [Lequesne]</td>
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<tr>
<td>M81.8</td>
<td>Other osteoporosis without current pathological fracture</td>
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<tr>
<th>HCPCS Level II</th>
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<tbody>
<tr>
<td>J0897</td>
<td>Subcutaneous, denosumab, 1 mg</td>
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<tr>
<td>J1740</td>
<td>Injection, ibandronate sodium, 1 mg</td>
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</tr>
<tr>
<td>J3110</td>
<td>Subcutaneous, teriparatide, 10 mcg</td>
<td></td>
</tr>
<tr>
<td>J3489</td>
<td>IV, zoledronic acid, 1 mg</td>
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