Annual Review of Osteoporosis Medications - Fiscal Year 2011

Oklahoma HealthCare Authority March 2012

Current Prior Authorization Criteria

| Tier 1* | Tier 2 | Tier 3 |
|------------------------|------------------------------|--|
| Alendronate (Fosamax®) | Alendronate + D (Fosamax®+D) | Zoledronic acid (Reclast®) |
| Calcium + Vitamin D† | Ibandronate (Boniva®) | Teriparatide (Forteo®) |
| | Risedronate (Actonel®) | Prolia ™ (Denosumab) |
| | | Risedronate delayed release (Atelvia™) |

Mandatory Generic Plan Applies.

- 1. Treatment failure with all lower tiered products, or
- 2. Contraindication to all lower tiered products, or
- 3. Allergic reaction to all lowered tiered products, or
- 4. Specific indication not covered by a lower tiered product.
- 5. No concomitant use of bisphosphonate therapy will be approved. No additional bisphosphonate may be approved for 365 days following zoledronic acid infusion.
- 6. Clinical Exceptions:
 - a. **Risedronate** may be approved for members with high risk for gastric side effects.
 - b. **Zoledronic acid** may be approved for members with a diagnosis of Paget's disease or for osteoporosis if secondary diagnosis meets criteria below:
 - i. Severe esophageal disease (e.g., ulcerations, strictures)
 - ii. Inability to take anything by mouth
 - iii. Inability to sit or stand for prolonged periods
 - iv. Inability to take an oral bisphosphonate for other special medical circumstances that justify the method of administration
 - c. **Teriparatide** requires a BMD test (T-score at or below -2.5) within the last month, and a minimum 12 month trial with a bisphosphonate plus adequate calcium and vitamin D, and a 12 month trial of Prolia™ (Denosumab), unless contraindicated, intolerant, or allergic, that did not yield adequate results.
- 7. Quantity Limits apply based on FDA maximum doses.

^{*}Calcitonin and raloxifene are not included as Tier 1 trials.

[†]Must be used at recommended doses in conjunction with Tier 1 bisphosphonate for trial to be accepted unless member has a recent laboratory result showing adequate Vitamin D or member is unable to tolerate calcium. OTC Calcium and Vitamin D are only covered for members with osteoporosis.

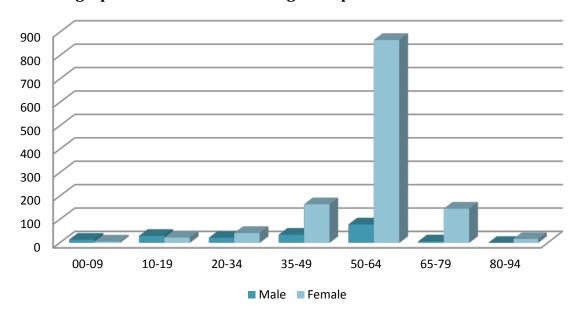
Utilization of Osteoporosis Medications

Comparison of Fiscal Years

| Fiscal Year | | Members* | Claims | Cost | Cost/Claim | Perdiem | Units |
|-------------|----------|----------|--------|--------------|------------|---------|--------|
| 2010 | Pharmacy | 1,569 | 7,756 | \$475,107.96 | \$61.26 | \$2.06 | 91,202 |
| | Medical | 6 | 6 | \$5,088.52 | \$848.09 | N/A | 24 |
| | Total | 1,575 | 7,759 | \$480,196.48 | \$61.89 | N/A | N/A |
| 2011 | Pharmacy | 1,453 | 7,467 | \$344,757.00 | \$46.17 | \$1.62 | 67,547 |
| | Medical | 7 | 7 | \$5,662.46 | \$808.92 | N/A | 31 |
| | Total | 1,460 | 7,474 | \$350,419.46 | \$46.89 | N/A | N/A |
| % Change | | -7.3 | -3.7 | -27.0 | -24.2 | N/A | N/A |
| Change | | 115 | 285 | \$129,777.02 | \$15.00 | N/A | N/A |

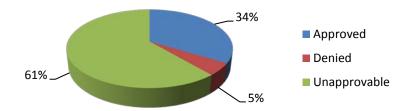
^{*}May be duplications between Pharmacy and Medical claims.

Demographics of Members Utilizing Osteoporosis Medications: FY 2011

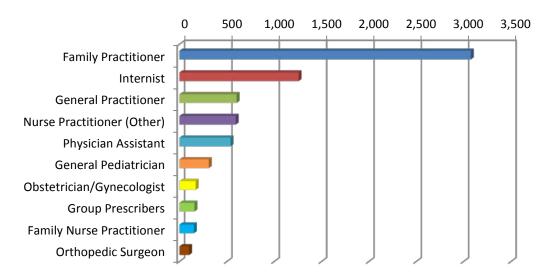


Status of Petitions for Osteoporosis Medications: FY 2011

There were a total of 279 petitions submitted for this PBPA category during Fiscal Year 2011. The following chart shows the status of the submitted petitions.



Top 10 Prescribers of Osteoporosis Medications by Number of Claims*: FY 2011



^{*}Pharmacy claims only

Market News and Update

On October 13, 2010, a label change for bisphosphonates was made regarding the risk of atypical fractures of the thigh. These fractures are uncommon and account for less than 1% of all hip and femur fractures overall. It is not clear if bisphosphonates are the cause, however they are reported predominately in patients taking bisphosphonates.

On July 21, 2011 an adiitional warning was issued for bisphosphonates regarding the risk of cancer of the esophagus. The FDA is continuing to evaluate as this has not been confirmed.

Conclusion and Recommendations

The College of Pharmacy recommends no changes to the current prior authorization criteria.